POMERANTZ LLP
Josh Silverman (*pro hac vice*)
Louis C. Ludwig
10 South LaSalle St., Ste. 3505
Chicago, IL 60603
Telephone: (312) 377-1181
jpsilverman@pomlaw.com
lcludwig@pomlaw.com

ROCHE FREEDMAN LLP
Ivy T. Ngo (*pro hac vice*)
Velvel (Devin) Freedman (*pro hac vice*)
Constantine P. Economides (*pro hac vice* forthcoming)
1 SE 3rd Ave., Suite 1250
Miami, Florida 33131
Telephone: (305) 971-5943
ingo@rochefreedman.com
vel@rochefreedman.com
ceconomides@rochefreedman.com

Counsel for Lead Plaintiff and the Class

- additional counsel on signature page -

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE CORMEDIX INC. SECURITIES LITIGATION	Case No. 2:21-cv-14020 JXN CLW **CLASS ACTION**
THIS DOCUMENT RELATES TO: ALL CASES	SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT Honorable Julien Neals **JURY TRIAL DEMANDED**

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Lead Plaintiff John V. Levon ("Plaintiff"), by and through his undersigned attorneys, on behalf of himself and all others similarly situated, alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, *inter alia*, review of defendants' public documents, conference calls and announcements made by defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and about CorMedix Inc. ("CorMedix" or the "Company"), analysts' reports and advisories about CorMedix, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action brought on behalf of two proposed classes (the "Classes"):

> All persons and entities, other than Defendants, who purchased CorMedix securities pursuant or traceable to the Company's November 27, 2020 "At the Market" ("ATM") offering ("Offering") pursuant to CorMedix's Form S-3 Registration Statement, its Prospectus Supplement, dated November 27, 2020, and its Prospectus Supplement, dated August 12, 2021 (together, the "Offering Documents"). This class only asserts claims for violations of §§ 11 and 15 of the Securities Act of 1933 ("1933 Act"), 15 U.S.C. §§ 77k and 77o ("1933 Act Class"); and
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> All persons and entities, other than Defendants, that purchased or otherwise acquired CorMedix securities between October 16, 2019 and August 8, 2022, both dates inclusive ("Class Period"). This class only asserts claims for

violations of §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 ("1934 Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.1 b-5 ("1934 Act Class").

2. For the last decade, CorMedix has primarily focused on developing its lead product candidate, Neutrolin® ("Neutrolin"), a purportedly novel antibacterial and antifungal solution designed to prevent costly and dangerous catheter-related bloodstream infections ("CRBSIs") and thrombosis in patients requiring central venous catheters in clinical settings such as hemodialysis, critical/intensive care, and oncology—a catheter lock solution ("CLS").

3. CorMedix has been selling Neutrolin commercially in Germany since December 2013, after receiving CE-Mark approval in July 2013 and label expansion in September 2014 in the European Union (EU) and in December 2014 in Germany. CorMedix then expanded to other EU countries and the Middle East after Hemotech SAS became its marketing partner in April 2017 and launched Neutrolin in France and certain overseas territories. CorMedix has always manufactured Neutrolin through third-party commercial manufacturing organizations ("CMOs").

4. Simultaneously, in late 2013, CorMedix began actively pursuing U.S. approval of Neutrolin by meeting with the U.S. Food and Drug Administration ("FDA").[1] Despite the CorMedix Defendants' Class Period assurances about their

[1] The Food, Drug and Cosmetic Act ("FD&C Act") created the FDA to "protect the public health" by ensuring that "drugs are safe and effective." 21 U.S.C. §

past successful manufacturing and regulatory experience and the FDA's support for its manufacturing program, the Company has never had a demonstrably consistent manufacturing process for its lead drug product, as FDA regulations require.[2] While raising money through public offerings, downplaying FDA requests for more information, and concealing deficiencies at its manufacturers' facilities, CorMedix submitted a highly risky New Drug Application ("NDA") for its lead drug product that was not likely to be approved by the FDA and left investors holding empty bags when the Company received not one, ***but two*** Complete Response Letters ("CRLs"), denying approval of the NDA due to identified deficiencies relating to its manufacturing information and facilities.

5. Drug sponsors seeking FDA approval of a new drug for U.S. sale, marketing, and commercial distribution must submit an NDA. The FDA has made clear that through the NDA process, drug sponsors must show that: (i) a drug is effective and safe in its proposed use(s), and its benefits outweigh its risks; (ii) the drug's proposed labeling is appropriate, and what it should contain; and (iii) the methods used to manufacture the drug and the controls used to maintain its quality

393(b)(2)(B). The FD&C Act prevents the "introduce[tion] or deliver[y] for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to [this section] is effective with respect to such drug." 21 U.S.C. § 355(a).

[2] The "CorMedix Defendants" are CorMedix, Khoso Baluch, Robert Cook, Phoebe Mounts, John L. Armstrong, Matthew David, and Joe Todisco. *See infra,* ¶¶41-49.

are adequate to preserve its identity, strength, quality and purity.[3]

6. To make that showing, an NDA must include data generated from successful clinical trials[4] and demonstrate adequate Chemistry, Manufacturing and Controls ("CMC") to ensure that the drug is consistently effective, safe, and high quality. CMC encompasses the entire product lifecycle – from clinical trials through post-approval and beyond – to sustain a connection between the drug being investigated in clinical studies and the drug being commercially marketed and sold. CMC applies to the drug ***and*** the facilities manufacturing the drug.

7. About six months before a planned NDA submission date, the FDA's CMC review team will meet with a drug sponsor to discuss potential issues to ensure the submission of a complete NDA.[5] CMC issues that may arise include: (i) the relationship between the drug's manufacturing, formulation, and packaging used in Phase III studies and as it will be marketed and sold, and whether any previously agreed upon comparability or bridging studies were completed; (ii) whether the

[3] U.S. FOOD & DRUG ADMIN., *New Drug Application (NDA)* (June 10, 2019), https://www.fda.gov/drugs/types-applications/new-drug-application-nda.

[4] U.S. FOOD & DRUG ADMIN., *What Are the Different Types of Clinical Research?* (Jan. 4, 2018), https://www.fda.gov/patients/clinical-trials-what-patients-need-know/what-are-different-types-clinical-research.

[5] U.S. DEPT. OF HEALTH AND HUMAN SERVICES, *Guidance for Industry – IND Meetings for Human Drugs and Biologics* (May 2001), https://www.fda.gov/files/Guidance-for-Industry---IND-Meetings-for-Human-Drugs-and-Biologics---Chemistry--Manufacturing--and-Controls-Information-%28PDF%29.pdf.

NDA will contain adequate stability data according to protocols the FDA previously approved; (iii) whether all facilities (*e.g.*, manufacturing, testing, packaging) will be ready for inspection by the time of the NDA submission; and (iv) any other issues, potential problems, or regulatory issues raised by the FDA or sponsor.

8. Before the Class Period began, CorMedix appeared to be successfully developing Neutrolin for the U.S. market. The Company had received FDA approval to initiate a Phase 3 clinical trial (LOCK-IT-100) in October 2014,[6] which launched in December 2015 and yielded enough data by July 2019 to support an NDA submission.[7] The Company also got Neutrolin designated as a Qualified Infectious Disease Product ("QIDP") and approved for Fast Track in January 2015.[8]

9. After completing its clinical trials, CorMedix began to focus on ensuring its commercial manufacturing met FDA standards – making it clear to

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[6] *CorMedix Receives Approval from FDA to Initiate a Clinical Trial for Neutrolin in the US*, YAHOO!FINANCE (Oct. 27, 2014), https://finance.yahoo.com/news/cormedix-receives-approval-fda-initiate-125029532.html.

[7] *Cormedix Receives Encouraging FDA Feedback on Neutrolin® Lock-It-100 Data*, CORMEDIX, INC. (Jul. 9, 2019), https://www.cormedix.com/cormedix-receives-encouraging-fda-feedback-neutrolin-lock-100-data/.

[8] QDIP provides five years of marketing exclusivity on top of the five years granted upon NDA approval; Fast Track facilitates the development of drugs intended to address an unmet medical need and provides eligibility for priority review of the marketing application. *See* U.S. FOOD & DRUG ADMIN., *Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review* (Feb. 23, 2018), https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review.

investors that the Company knew what it was doing in that regard. In August 2019, Defendant Jack L. Armstrong, the Company's Executive Vice President (EVP) of Technical Operations since 2017, specifically assured investors that:

> ***CorMedix has been manufacturing and selling Neutrolin outside the U.S. for the last five years. We have successfully carried out technical transfer and validation of the manufacturing process, which has enabled the successful production of product at three different manufacturing sites***. This should give you comfort that we understand Neutrolin's manufacturing, technical, analytical processes as well as the quality controls and the systems that go with it. … And importantly, the key members of my staff, including me, have in our past experience, successfully submitted multiple NDAs that were ultimately approved.

10. Thus, on the first day of the Class Period, October 16, 2019, CorMedix seemed to have all the data, processes and controls – including the manufacturing information – needed to submit a successful NDA for Neutrolin when it issued a press release announcing a "Successful CMC Interaction with the FDA[.]" The Company claimed that "[t]he FDA was supportive of Neutrolin's proposed manufacturing program, including the active pharmaceutical ingredients (API), the container closure and testing," and "[n]o further CMC meetings with FDA [we]re planned prior to NDA submission." On this announcement, CorMedix's stock price increased over 9%.

11. Then, during the first earnings call of the Class Period, on November 14, 2019, while reiterating that "[a]s our press release of 16 October indicated[,] the outcome of our interaction with the FDA was very positive[,]" the "FDA was

supportive of the core manufacturing processes for the drug product," and "[n]o further CMC meetings with FDA are planned prior to the NDA submission," Defendant Armstrong noted that that "FDA did request some additional data which we are working to complete." He did not, however, elaborate on the specific nature of the requested "additional data."

12. While hinting at a possible issue in CorMedix's CMC module for Neutrolin that concerned the FDA enough to request more information, Armstrong quickly reassured investors of the Company and its manufacturing team's proven "breadth and depth in the requirements for sourcing, manufacturing, distribution and quality assurance," reiterating its five-year track record of successfully manufacturing and selling Neutrolin outside the U.S., and its success in completing "technical transfer and validation of the manufacturing process" which enabled "the successful production of product at three different manufacturing sites."

13. As the market absorbed these and other positive statements about how the Company's manufacturing was on track for a successful NDA submission, its stock jumped 24% over the next two trading days.

14. After the FDA accepted the Neutrolin NDA for rolling review in February 2020, CorMedix began its submission the next month, completing it in June 2020. At the same time, the FDA begun to substantively review the NDA and engaged in ongoing dialogue with the Company to determine, *inter alia*, whether the

facility that would be manufacturing, processing, packaging, or holding Neutrolin met FDA standards designed to assure its continued safety, quality, and purity.

15. By May 2020, the FDA had conditionally approved DefenCath™ ("DefenCath") as the U.S. proprietary name for Neutrolin. In the same month, the Company formed a wholly owned subsidiary in Spain, CorMedix Spain, S.L.U., apparently to better oversee and/or manage its CMO for its U.S. drug product as well as its API heparin manufacturer as the COVID-19 pandemic spread globally.

16. In the face of challenges caused by the pandemic, on July 8, 2020, the CorMedix Defendants highlighted to investors their ability to submit a complete NDA and portrayed the Company and its CMO as having successfully collected the information and/or data required to meet FDA standards: all that was left was approval. On this news, CorMedix's stock price increased 7%.

17. Throughout the rest of the Class Period, the CorMedix Defendants touted more milestones that maintained or increased the Company's stock price while regularly noting that the FDA "had not identified any potential review issues":

- 8/31/20: CorMedix announced that the FDA had accepted the DefenCath NDA for filing and granted it Priority Review with a Prescription Drug User Fee Act ("PDUFA") date of February 28, 2021.[9]
- 11/18/20: CorMedix announced that an advisory committee meeting for

[9] Under Priority Review, the FDA reduces its review time from ten months to six. *See* U.S. FOOD & DRUG ADMIN., *Priority Review* (Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review.

the DefenCath NDA was not needed.

18. Capitalizing on its stock price, CorMedix conducted a public offering on July 29, 2020, an ATM offering, originally issued on November 27, 2020, and supplemented on August 12, 2021 ("Offerings").

19. Based on well-established current Good Manufacturing Practice ("cGMP") standards and the Company's ongoing dialogue with the FDA, the Officer Defendants were ultimately responsible for ensuring processes were in place to assure the control of outsourced activities (*e.g.*, manufacturing) and quality of purchased substances (*e.g.*, heparin). Unbeknownst to investors, however, the CorMedix Defendants submitted the DefenCath NDA without competently verifying its completeness or maintaining sufficient processes and controls to ensure contracting facilities had met and would continue to meet FDA standards for commercial readiness. At the same time, Defendants raised funds by conducting Offerings, and improperly benefited from the inflated share price caused by the CorMedix Defendants' misstatements and/or omissions of material facts concerning the CMC information provided in the NDA and the capabilities of the Company's manufacturers.

20. Investors were thus shocked when, on March 1, 2021, CorMedix issued a press release announcing the existence of manufacturing deficiencies which warranted a CRL instead of FDA approval (the "First CRL"). The Company

detailed, *inter alia*, that the "FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility" and the "FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications."[10]

21. On this news, CorMedix's stock price fell nearly 40% on March 1, 2021. As one industry analyst explained, the "CRL due to third party manufacturing issues … ***comes as a surprise as the product has already been in production and commercial in the EU, albeit at limited capacity.***" (Emphasis in original).

22. While conceding their knowledge of the FDA's request for more information from their CMO, the CorMedix Defendants assured industry analysts (and investors) that "the CMO manufactures drugs sold in the U.S.[,] implying some level of FDA inspection in the past that passed FDA's standards" and "the CMO is experienced in handling drug/device combos similar in scope to DefenCath."

23. And during the Company's first call with analysts and investors after the First CRL on March 9, 2021, the CorMedix Defendants downplayed the issues

[10] *CorMedix Receives Complete Response Letter from FDA for DefenCath™ Catheter Lock Solution*, GLOBENEWSWIRE (Mar. 1, 2021, 08:30 ET) ("3/1/21 Press Release"), https://www.globenewswire.com/en/news-release/2021/03/01/2184292/0/en/CorMedix-Receives-Complete-Response-Letter-From-FDA-for-DefenCath-Catheter-Lock-Solution.html.

underlying the CRL, including that "one deficiency results from the proposed future installation of new equipment, but it was apparently not clear to FDA that the equipment is unrelated to the manufacturer of DEFENCATH" and that the additional requested manual extraction study and airflow visualization study would be "completed in the next several weeks." Based on these and other statements, industry analysts and investors believed that the "the manufacturing issues are straightforward and can be resolved within weeks."

24. That was not the case, however. As analysts and investors learned on April 14, 2021, CorMedix could not resubmit an NDA until the third quarter of 2021 ("3Q21") because it had to take additional steps for DefenCath's manufacturing process to meet regulatory standards, including "[a]ddressing FDA's concerns regarding the qualification of the filling operation [that] may necessitate adjustments in the process and generation of additional data on operating parameters for manufacture of DefenCath." On this news, CorMedix's stock price fell over 18%.

25. While disclosing that the Company's original proposed resolutions to the deficiencies underlying the First CRL were insufficient, the CorMedix Defendants assured investors that the Company was finally aligned with the FDA after "[k]ey representatives from both CorMedix and its CMO participated in a meeting…to address the deficiencies noted in the [First] CRL." As a result, industry analysts (and investors) were "confident that there [wa]s a clear resolution plan

agreed upon with the FDA to address the manufacturing CRL" and "anticipate[d] NDA resubmission in the next few months by around 3Q21 followed by FDA decision on the need for a site visit sometime in late 3Q21 or 4Q21[.]"

26. But then, on May 13, 2021, CorMedix disclosed it could not resubmit its NDA until the fourth quarter of 2021 ("4Q21") because "additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA." On this news, CorMedix's stock price fell nearly 20%.

27. The CorMedix Defendants, however, continued to tout the Company and its CMO's ability to resolve the manufacturing deficiencies and resubmit its NDA by the end of the year:

- 5/13/21: "[W]e have the right team and appropriate resources in place to resolve the third-party manufacturing deficiency."
- 8/12/21: "[W]e are on schedule to be able to resubmit the CorMedix NDA in quarter 4, 2021. … [W]e have the right team and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified[.]"

28. Industry analysts, and investors, still believed the CorMedix Defendants, particularly because they appeared to be intimately involved in resolving the manufacturing deficiencies rather than just leaving it to the CMO:

- 5/14/21: "Most importantly, the company is making good progress toward resubmission of the Defencath NDA, including completion of the manual extraction study. The company is advancing process qualification and validation activities, based on which it now expects to resubmit the Defencath NDA in 4Q21." (JMP Securities)

- 8/12/21: "Company remains on track to submit NDA in 4Q21. …[T]he process qualification of vial filling process appears to be in progress by the CMO with inputs from [CorMedix] and outside consultant." (Truist Securities)
- 8/13/21: "The remaining process qualification and validation work requested by FDA is being completed by the third-party facility, in close collaboration with the CMC and regulatory teams of CorMedix and CMC consultants. CorMedix management affirmed that it remains in agreement with the third-party manufacturer on the appropriate steps to resolve the FDA's concerns. CorMedix is also working with the manufacturing facility to prepare for a potential on-site or remote inspection by the FDA." (JMP Securities)

29. But investors learned on September 7, 2021 that not only had CorMedix "encountered delays at its third-party [CMO]," but that "the timeline for CorMedix and the CMO to address deficiencies at the facility that are required for resubmission of the DefenCath NDA is uncertain[.]" On this news, CorMedix's stock price fell over 27%.

30. Moreover, these delays in resolving the manufacturing deficiencies underlying the First CRL and resubmitting the DefenCath NDA indicated that CorMedix did not have the "right team" to resolve the deficiencies, as confirmed on October 4, 2021. That day, CorMedix announced that, effective immediately, Defendant Baluch was retiring as CEO and resigning from the Company's Board of Directors ("Board") and Defendant Armstrong was retiring from CorMedix.

31. CorMedix again confirmed that it did not have the "right team" to resolve the manufacturing deficiencies identified by the FDA when on November 9,

2021, Defendant Mounts admitted that "we have engaged [a] team of external consultants to provide additional expertise on FDA's expectations for addressing the specific deficiencies at the manufacturing facility, and to assist in preparations for a pre-approval inspection."

32. The CorMedix Defendants' assurances about manufacturing after the First CRL, and each subsequent delay, was intended to and did lead investors to believe that the Company had finally done what it needed to according to FDA standards when it announced its resubmission of the DefenCath NDA on February 28, 2022, and the FDA's acceptance for review on March 28, 2022. After markets closed on August 8, 2022, however, CorMedix revealed that, in addition to, identified deficiencies at one of its key drug substance manufacturing facilities, manufacturing issues **still** existed at its CMO's facility, when it disclosed the Company had received yet another CRL "from the FDA stating that the DefenCath NDA cannot be approved until deficiencies recently conveyed to the [CMO] and the supplier of the [API] heparin during inspections are resolved to the satisfaction of FDA."[11] And its CMO also needed "an independent CGMP consultant to expedite the implementation of corrective actions."

[11] *CorMedix Inc. Announces Regulatory and Manufacturing Updates* GLOBENEWSWIRE, (Aug. 8, 2022) ("8/8/22 Press Release"), https://www.globenewswire.com/news-release/2022/08/08/2494270/0/en/CorMedix-Inc-Announces-Regulatory-and-Manufacturing-Updates.html.

33. Investors were stunned. CorMedix's stock price plummeted over 57% in response.

34. In sum, throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business and operations. Specifically, they made material misstatements and/or failed to disclose material facts, including that: (i) deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iii) the DefenCath NDA reflected those deficiencies; (iv) because of the foregoing deficiencies, the DefenCath NDA was at a substantial risk of being rejected by the FDA; (v) despite the First CRL, the CorMedix Defendants downplayed the true scope of the deficiencies identified with regards to, the manufacturing process set forth in the NDA, and the facility manufacturing DefenCath; (vi) upon learning of new equipment at the CMO facility, the CorMedix Defendants failed to take necessary steps to ensure that the CMO's quality assurance protocols relating to changeover of manufacturing lines and visual inspections of drug products met cGMP standards; (vii) as a result of deficient protocols, the CMO manufactured contaminated vials in July 2021, which delayed the Company's ability to obtain

necessary validation data for resubmission of the DefenCath NDA; (viii) the CMO's facilities continued to be cGMP non-compliant, as the FDA's on-site inspection confirmed; (ix) the FDA had observed manufacturing deficiencies at the Company's third-party facility supplying heparin, which warranted the issuance of a Form 483 on February 4, 2022, and added to the substantial risk of the FDA denying the DefenCath NDA for a second time; and (x) as a result, the Company's public statements were materially false and misleading statements and/or omissions at all relevant times.

35. As a result of Defendants' misstatements and/or omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

36. The claims asserted herein arise under and pursuant to §§ 11 and 15 of the 1933 Act (15 U.S.C. §§ 77k and 77o), and §§ 10(b) and 20(a) of the 1934 Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

37. This Court has jurisdiction over the subject matter of this action pursuant to § 22 of the 1933 Act, § 27 of the 1934 Act, and 28 U.S.C. § 1331.

38. Venue is proper in this Judicial District pursuant to § 22 of the 1933 Act, § 27 of the 1934 Act, and 28 U.S.C. § 1391(b). In this Judicial District is where

CorMedix is headquartered, Defendants conduct business, and a significant part of the acts and conduct complained of herein took place.

39. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

A. Plaintiff

40. Plaintiff purchased CorMedix securities at artificially inflated prices during the Class Period and traceable to the Offering Documents, as set forth in his certification attached hereto, and was damaged thereby, upon the revelation of the alleged corrective disclosures.

B. Defendants

1. CorMedix

41. Defendant CorMedix is a biopharmaceutical company that focuses on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases in the U.S. and internationally. The Company is a Delaware corporation with principal executive offices located at 300 Connell Drive, Suite 4200, Berkeley Heights, New Jersey 07922. The Company has two wholly owned subsidiaries: CorMedix Europe GmbH (formed in 2013) and

CorMedix Spain, S.L.U. (formed in May 2020). The Company's common stock trades in an efficient market on the Nasdaq Stock Market ("NASDAQ") under the ticker symbol "CRMD." Prior to February 2, 2021, the Company's common stock traded on the NYSE American ("NYSE") under the same ticker symbol.

2. The Officer Defendants

42. Defendant Khoso Baluch ("Baluch") served as CorMedix's Chief Executive Officer ("CEO") and on its Board from October 2016 until he retired, effective October 4, 2021. Baluch signed the Registration Statement for the Offering. Prior to joining CorMedix, Baluch served as Senior Vice President ("SVP") and President, Europe, Middle East & Africa, and Chief Marketing Officer of UCB, SA. Baluch also worked for Eli Lilly and Company for 24 years, holding international positions spanning Europe, the Middle East and the U.S. in general management, business development, market access and product leadership.

43. Defendant Robert Cook ("Cook") served as CorMedix's Chief Financial Officer ("CFO") from February 1, 2017, until his employment agreement expired on January 31, 2020. Prior to joining CorMedix, Cook served as CFO of Bioblast Pharma Ltd.; CFO and EVP at Strata Skin Sciences, Inc.; SVP and CFO at Immune Pharmaceuticals, Inc.

44. Defendant Matthew David ("David") has served as CorMedix's CFO and EVP since May 2020, and signed public filings incorporated into the Offering

Documents. David joined CorMedix after serving as Head of Strategy at Ovid Therapeutics Inc, a late-stage clinical biopharmaceutical company, where he was responsible for financing strategy and investor relations.

45. Defendant Phoebe Mounts ("Mounts") was, at all relevant times, serving as EVP, General Counsel, and Secretary of CorMedix as well as its Head of Regulatory, Compliance & Legal. Prior to CorMedix, Mounts was a partner at Morgan, Lewis & Bockius LLP, where she had been providing legal services to the Company as outside counsel since 2013, with responsibility for developing its FDA regulatory strategies for Neutrolin.

46. Defendant John L. Armstrong (also referred to as "Jack") ("Armstrong") served as EVP for Technical Operations of CorMedix from March 2017 until his premature retirement, effective October 4, 2021. Prior to that, he was employed by the Company as a consultant beginning in November 2014, performing the same services that he performed as CorMedix's EVP for Technical Operations. The Company touted Armstrong's more than 45 years of experience in the pharmaceutical industry with broad senior level cross functional experience, as well as his having held a number of general management positions. Prior to joining the Company, he was President of Correvio, a private pharmaceutical company supplying product to over 50 countries; President/CEO of Genaera Corporation; SVP of Urocor Corporation; CEO of Mills Biopharma; President of Oread CMO;

President of Endo Laboratories (subsidiary of DuPont Merck); President of World-wide Manufacturing for DuPont Merck Pharmaceuticals; and Vice President Operations for Marion/Marion Merrill Dow. Armstrong also held various roles in manufacturing, quality assurance, led integrated business systems development for three companies as well as having expertise in business development. He is also a CPIM (Certified in Production and Inventory Management).

47. Pursuant to his Employment Agreement with the Company, executed on April 23, 2020, Armstrong was to serve as its EVP for 3 years, until April 2023. In announcing the agreement, CorMedix stated, in relevant part, that his "experience will be critical as we continue our preparations to commercialize Neutrolin, whether on our own or with a strategic or commercial partner."[12]

48. Defendant Joseph Todisco ("Todisco") has served as CorMedix's Chief Executive Officer ("CEO") and on its Board since May 10, 2022. Prior to joining CorMedix, Todisco served as a senior executive at Amneal Pharmaceuticals, where for the past 11 years he held various roles, most recently EVP, Chief Commercial Officer. Prior to that, Todisco was VP, Business Development and

[12] *CorMedix Inc. Announces Contract Extension of Jack Armstrong as Executive Vice President and Head of Technical Operations*, GLOBENEWSWIRE (Apr. 23, 2020, 08:15 ET), https://www.globenewswire.com/news-release/2020/04/23/2020918/0/en/CorMedix-Inc-Announces-Contract-Extension-of-Jack-Armstrong-as-Executive-Vice-President-and-Head-of-Technical-Operations.html.

Licensing at Ranbaxy, Inc. Todisco was also previously co-founder and managing executive of Gemini Laboratories.

49. Defendants Baluch, Cook, David, Mounts, Armstrong, and Todisco are referred to herein as the "Officer Defendants" and collectively with CorMedix, are referred to herein as the "CorMedix Defendants."

50. The adverse developments at issue here impacted the most central aspect, or the core, of CorMedix's business, operations, and revenue. Due to its prior financial struggles, the Company was particularly incentivized to take advantage of its U.S. prospects. During the Class Period, the CorMedix Defendants' communications to the public almost exclusively concerned the DefenCath NDA, and they repeatedly emphasized the Company's expertise and progress in developing and commercializing DefenCath for U.S. marketing. Moreover, while the Company was waiting for a decision from the FDA, it needed liquidity to stay afloat, and to raise capital at favorable terms, it needed to keep its stock price as high as possible.

51. As a result, the success of the DefenCath NDA was highly material to CorMedix's business during the Class Period. Indeed, it represented to investors that all its products besides DefenCath had an "immaterial" impact on its financial performance and business prospects. If CorMedix was not able to commercialize its main product in the U.S., it would have a material impact on the Company's profits and operations for the simple reason that DefenCath was, at least during the relevant

time period, the Company's sole focus. Indeed, during the Class Period, CorMedix focused nearly all of its manufacturing and product marketing to support the commercialization of DefenCath.

52. Analysts following the Company confirmed the paramount importance of achieving FDA approval of DefenCath and the sole focus of CorMedix developing, marketing, and selling DefenCath in the U.S.

53. Given the substantial importance of FDA approval for DefenCath to the Company's financial performance, there is no doubt that the CorMedix Defendants had processes and procedures in place to immediately be made aware of any concerns raised by the FDA regarding meeting CMC standards at any facility manufacturing DefenCath or its API heparin. If Defendants lacked such processes and procedures, Defendants were reckless in not establishing them, and in not informating investors that they lacked such crucial controls.

54. The Officer Defendants possessed the requisite scienter as they had the power and authority to control the contents of CorMedix's SEC filings, press releases, and other market communications. They were provided with copies of CorMedix's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with CorMedix, and their access to material information available to them but not to the public, the

Officer Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Officer Defendants are liable for the false statements and omissions pleaded herein.

55. Likewise, as alleged herein, the CorMedix Defendants acted with scienter in that they knew the public documents and statements disseminated or issued in the name of the Company were materially false and misleading; knew that such statements or documents would be disseminated or issued to the investing public; and knowingly and substantially participated or acquiesced in disseminating or issuing of such statements or documents and in actions intended to manipulate the market price of CorMedix securities as primary violations of the securities laws.

56. The allegations herein also establish a strong inference that CorMedix as an entity acted with corporate scienter throughout the Class Period. Its officers, management, and agents, including, but not limited to, the Officer Defendants, had actual knowledge of the misrepresentations and omissions of material facts set forth herein (for which they had a duty to disclose), or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing the concerns raised by the FDA from the investing

public. Indeed, the FDA would have only communicated about those CMC issues with senior individuals at CorMedix who were in a position to establish its scienter. By concealing these material facts from investors, CorMedix maintained and/or increased its artificially inflated common stock prices throughout the Class Period.

57. Moreover, given the extensive communications that the Officer Defendants had with analysts and investors, including Plaintiff, and the detail of their representations regarding their attention to detail and review of CMC standards, they each made themselves aware of the Company's and FDA's actual (but undisclosed) findings with respect to the CMC data presented or had no factual basis to make such specific quantitative statements. In either event, the Officer Defendants were at least reckless with respect to the truth, and their scienter is imputable to the Company.

3. The Director Defendants

58. Defendant Janet Dillione ("Dillione") served as a director of CorMedix at all relevant times, and signed the Registration Statement and/or other public filings incorporated in the Offering Documents.

59. Defendant Myron Kaplan, M.D. ("Kaplan") served as a director of CorMedix at all relevant times and signed the Registration Statement and/or other public filings incorporated in the Offering Documents.

60. Defendant Alan W. Dunton, M.D. ("Dunton") served as a director of CorMedix at all relevant times and signed the Registration Statement and/or other

public filings incorporated in the Offering Documents.

61. Defendant Steven Lefkowitz ("Lefkowitz") served as a director of CorMedix at all relevant times and signed the Registration Statement and/or other public filings incorporated in the Offering Documents.

62. Defendant Paulo F. Costa ("Costa") served as a director of CorMedix at all relevant times and signed the Registration Statement and/or other public filings incorporated in the Offering Documents.

63. Defendant Greg Duncan ("Duncan") served as a director of CorMedix at all relevant times and signed the Registration Statement and/or other public filings incorporated in the Offering Documents.

64. Defendants Dillione, Kaplan, Dunton, Lefkowitz, Costa, and Duncan are referred to herein as the "Director Defendants."

65. The Director Defendants each participated in preparing, and signed and/or authorized the signing of, the Company's Offering Documents. By virtue of their positions as directors of the Company, the Director Defendants were control persons of CorMedix. They each had direct and/or indirect business and/or personal relationships with other directors, officers, and/or major shareholders of CorMedix. Because of their positions with CorMedix, and their access to material information available to them but not to the public, the Director Defendants knew of, or in the exercise of reasonable care should have known of, the existing yet undisclosed

conditions and material risks detailed herein, which were either misrepresented in or omitted from the Offering Documents. As such, the Director Defendants are liable to Plaintiff and those similarly situated under the 1933 Act.

IV. THE 1933 ACT CLAIMS

A. Substantive Allegations Under the 1933 Act

66. This part of the Complaint only asserts strict liability and negligence claims based on the 1933 Act and neither alleges, nor sounds in, fraud.

67. As detailed below, the Offering Documents were negligently prepared and as a result contained untrue statements of material fact, omitted to state other facts necessary to make statements not misleading, and were not prepared according to the rules and regulations governing the Offering Documents preparation.

68. For example, the Offering Documents failed to disclose that CorMedix knew or should have known before the effective date of the Offering Documents that its DefenCath NDA did provide sufficient CMC data necessary to achieve regulatory approval as the Company had represented, and that CorMedix was at risk of receiving a CRL from the FDA, delaying the approval process. In fact, as explained herein, the Offering Documents falsely and misleadingly represented contrary facts.

69. Any information concerning FDA approval of the Company's NDA for DefenCath, particularly information indicating that the NDA was incomplete and provided insufficient information and/or data as required by the FDA as represented

to the market, was highly material to investors, because CorMedix's business model was primarily focused on achieving FDA approval and the entire thrust of its business was motivated by the development and commercialization of DefenCath in the U.S. Thus, any risk that the Company would be unable to market DefenCath domestically would be devastating to its business and future prospects.

1. CorMedix's pursuit of FDA approval of DefenCath

70. The Company has been developing its primary candidate, Neutrolin (later known as DefenCath) for the last decade, if not longer, claiming it will address a large unmet medical need and market opportunity. CorMedix's pursuit of U.S. marketing approval for its lead product candidate began in late 2013, when the Company met with the FDA to determine the pathway forward for Neutrolin.

71. For decades, regulation and control of new drugs seeking to enter the U.S. market has been based on the FDA's approval of the NDA. The FD&C Act prohibits any person from introducing or delivering for introduction an adulterated—*i.e.*, drugs not manufactured in compliance with cGMP—or misbranded drug into interstate commerce.[13] As such, an NDA is required to provide sufficient evidence for the FDA to assess:

- Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.

[13] Section 301(a) of the FD&C Act.

- Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain.
- ***Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.***

72. Each NDA must provide certain information relating to the applicant's CMC, including but not limited to, the name and address of each manufacturer of the drug product and drug substance; a description of the manufacturing and packaging procedures and in-process controls for the drug product and drug substance; and the specifications necessary to ensure the identity, strength, quality, purity, and potency of the drug substance and drug product.[14] Data must be available to establish that the analytical procedures used in testing the drug product meet proper standards of accuracy, sensitivity, specificity, and reproducibility and are suitable for their intended purpose.[15]

73. Any party engaged in the manufacture of a drug is responsible for ensuring compliance with cGMP regulations for the manufacturing activities it performs.[16] The FDA's regulations recognize that drug sponsors commonly use contract facilities to perform some drug manufacturing activities.[17] Regardless, if a

[14] 21 CFR 314.50(d)(1) and 314.94(a)(9)(i).

[15] *See* 21 CFR 211.165(e) and 211.194(a)(2).

[16] *See* Section 501(a)(2)(B) of the FD&C Act; 21 CFR parts 210-211; 600.

[17] 21 CFR 200.10(b) and 211.22(a).

drug sponsor chooses to use a contract facility, the *drug sponsor* remains legally responsible for assessing the quality of drug products manufactured by the contract facility, including for final release.[18] FDA regulations require that the responsibilities and procedures of the drug sponsor's quality unit be in writing and that they be strictly followed.[19]

74. Therefore, for *both* the drug sponsor and any contract facilities that conduct manufacturing operations, cGMP "includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products."[20] To support proper oversight of manufacturing, quality control labs, quality assurance, regulatory affairs, and project management the drug sponsor's organization should be structured such that:

- Personnel involved in these key areas have relevant knowledge and experience, including technical expertise and authoring capabilities;
- Key oversight roles, including specific sponsor-CMO responsibilities, are well defined in the quality agreement; and
- Appropriate oversight details are documented through Standard Operating

[18] *See* U.S. Food & Drug Admin., *Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry* (Nov. 2016), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/contract-manufacturing-arrangements-drugs-quality-agreements-guidance-industry.

[19] 21 CFR 211.22(d).

[20] Section 501 of the FD&C Act as amended by the Food and Drug Administration Safety and Innovation Act (Public Law 112-144, Title VII, section 711).

Procedures ("SOPs").[21]

75. The FDA encourages drug sponsors and contract facilities to review FDA guidance documents for recommendations on achieving compliance with cGMP.[22] Various FDA guidance documents describe how quality management principles relate to contract manufacturing operations, including some of the roles and manufacturing activities of contract manufacturing parties.[23]

76. Likewise, guidances for industry developed by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH"), and adopted by the FDA, provide specific cGMP guidance with respect to contract manufacturing arrangements.

77. First, ICH guidance for industry *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients* states that drug sponsors should evaluate contract facilities to ensure that the sites comply with cGMP for specific

[21] *5 Steps to Quality Oversight of Pharmaceutical Contract Manufacturing Organizations (CMOs)*, COMPLIANCEONLINE https://www.complianceonline.com/resources/quality-oversight-of-pharmaceutical-contract-manufacturing-organizations.html.

[22] *See* U.S. FOOD & DRUG ADMIN., *Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry* (Nov. 2016), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/contract-manufacturing-arrangements-drugs-quality-agreements-guidance-industry.

[23] *See, e.g.,* guidance for industry *Cooperative Manufacturing Arrangements for Licensed Biologics*.

operations.[24] In that evaluation, a drug sponsor should learn general prerequisites about a contractor's experience and capabilities, including but not limited to, its:

- understanding of the regulatory environment in which a product will be evaluated;
- proper production environment to meet the product's specific requirements;
- process for authoring and/or transferring documents and/or batch records;
- practical experience relating to product specific analytical methods and validation;
- availability and staffing to formulate and fill when needed;
- ability to effectively address and correct manufacturing and/or laboratory issues; and
- system, process and/or procedures for maintaining privacy and confidentiality.[25]

78. ICH guidance for industry *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients* also recommends that drug sponsors have approved written agreements with contractors that define the manufacturing responsibilities in detail, including the quality measures, of each party. The written agreements should also describe how changes to processes,

[24] U.S. FOOD & DRUG ADMIN., *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients* (Sept. 2016), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q7-good-manufacturing-practice-guidance-active-pharmaceutical-ingredients-guidance-industry.

[25] *5 Steps to Quality Oversight of Pharmaceutical Contract Manufacturing Organizations (CMOs)*, COMPLIANCEONLINE https://www.complianceonline.com/resources/quality-oversight-of-pharmaceutical-contract-manufacturing-organizations.html.

equipment, methods, and specifications will be managed and permit the drug sponsor to audit its contractor's facilities for compliance with cGMP. In preparing the written agreements, the drug sponsor should learn about the contractors' prior experience with quality assurance; processes for addressing quality issues; and their ability to author deviations, corrective and preventative actions ("CAPAs"), out-of-specification test results, and/or change controls.

79. Second, ICH guidance for industry *Q9 Quality Risk Management* offers a systematic approach to quality risk management as part of an effective quality system.[26] It discusses quality risk management principles such as risk assessment, risk communication, and risk review and provides examples of tools that can be used to make effective and efficient risk-based decisions in, for example, auditing and arranging quality agreements with contract manufacturers.

80. Third, ICH industry guidance *Q10 Pharmaceutical Quality System* states that, as part of a pharmaceutical quality system, the *drug sponsor* is ultimately responsible for ensuring "processes are in place to assure the control of outsourced activities and quality of purchased materials."[27] Moreover, these processes should

[26] U.S. FOOD & DRUG ADMIN., *Q9 Quality Risk Management* (June 2006), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q9-quality-risk-management.

[27] U.S. FOOD & DRUG ADMIN., *Q10 Pharmaceutical Quality System* (Apr. 2009), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q10-pharmaceutical-quality-system.

incorporate quality risk management and include the following critical activities:

- Assessing the suitability and competence of potential contractors before outsourcing operations or selecting material suppliers. This can be accomplished through audits, material evaluations, or other qualification criteria.
- Defining the manufacturing responsibilities and communication processes for quality-related activities of the involved parties. For outsourced activities, these should be in a written agreement.
- Monitoring and reviewing the performance of the contract facility and identifying and implementing any needed improvements.
- Monitoring incoming ingredients and materials to ensure they are from approved sources using the agreed-upon supply chain.

81. A drug sponsor's "*[s]enior management* has the ultimate responsibility to ensure an effective pharmaceutical quality system is in place to achieve the *quality objectives*, and that roles, responsibilities, and authorities are defined, communicated, and implemented throughout the company." *Id*. (emphasis in original). As such, senior management should:

- Participate in the design, implementation, *monitoring, and maintenance* of an effective pharmaceutical quality system;
- Demonstrate strong and visible support for the pharmaceutical quality system and ensure its implementation throughout their organization;
- Ensure a *timely and effective communication and escalation process* exists to raise quality issues to the appropriate levels of management;
- Define individual and collective roles, responsibilities, authorities, and inter-relationships of all organizational units related to the pharmaceutical quality system and ensure these interactions are communicated and understood at all levels of the organization;
- Conduct management reviews of process performance and product quality and of the pharmaceutical quality system;

- Advocate for continual improvement; and
- Commit appropriate resources.

82. Senior management is also responsible for establishing a quality policy that describes the overall intentions and direction of the company related to quality. Specifically, the quality policy should include an expectation to comply with applicable regulatory requirements and should facilitate continual improvement of the pharmaceutical quality system. Included in this responsibility, the drug sponsor's senior management must ensure that the quality policy has been communicated to and understood by personnel at all levels in the company and should review the policy periodically for continuing effectiveness and suitability.

83. Likewise, senior management should ensure the quality objectives to implement the quality policy are well defined and communicated; are supported by all relevant levels of the company; align with the company's strategies; and are consistent with the quality policy. Senior management is responsible for providing appropriate resources and training to achieve the quality objectives; and for establishing performance indicators that measure the progress against quality objectives. Performance indicators should be actively monitored and assessed by senior management, regularly communicated, and acted upon as appropriate.

84. A drug sponsor or contract facility may make changes to a drug's manufacturing during the drug development process, such as a new manufacturing site, formulation, purification column, equipment, or components. However, when

changes are made, the sponsor and/or contractor must demonstrate that the changes will not have an adverse impact on the drug's quality, safety, and efficacy.

85. Once the NDA has been submitted for review, the FDA may choose to perform a pre-approval inspection ("PAI") to assist in its determination of proper compliance with cGMP regulations.[28] The FDA conducts domestic and international PAIs, and may inspect all facilities associated with an NDA, including drug component manufacturing (such as APIs, also known as, drug substances) and finished drug product manufacturing.[29]

86. The PAI process begins with the manufacturing facility obtaining approval of its written procedures related to production, quality control, and quality assurance, and any formulated supporting documentation therefrom.[30] Such written and approved procedures, and data therefrom, are necessary to identify potential quality problems which may link to other major systems for inspectional coverage. When possible, the FDA prefers to verify the manufacturers' adherence to written procedures through an on-site inspection. In advance of a site inspection, the FDA

[28] Denise DiGiulio, *What to Expect When Being Inspected*, U.S. FOOD & DRUG ADMIN., (July 15-16, 2015), https://www.fda.gov/media/92857/download.

[29] U.S. FOOD & DRUG ADMIN., *Compliance Program Guidance Manual – Chapter 46- New Drug Evaluation* (Apr. 12, 2010), https://www.fda.gov/media/71498/download.

[30] U.S. FOOD & DRUG ADMIN., *Compliance Program – Chapter 56 – Drug Quality Assurance, Drug Manufacturing Inspections* (Oct. 31, 2017), https://www.fda.gov/media/75167/download

may request and inspect additional records or information within a reasonable timeframe, within reasonable limits, and in a reasonable manner under § 704(a)(4) of the FD&C Act.[31]

87. Based on the totality of the information available, including the CMC information provided in the NDA and any additional information about the facility or site, the FDA will take one of the following actions:

[31] U.S. DEPT. OF HEALTH AND HUMAN SERVICES, *Guidance for Industry – Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection* (Oct. 2014) https://www.fda.gov/media/86328/download.

Planned Action	Facilities and Sites	Other FDA Drug Assessment Deficiencies
Approve the NDA	Available information supports the adequacy of the facilities and sites named in a pending application.	No deficiencies have been identified and the NDA otherwise satisfies the requirements for approval.
Issue a CRL with facility or site deficiencies	Available information from a prior inspection or other source identifies deficiencies about the facility or site, but the required inspection cannot be completed due to factors including travel restrictions.	If any other deficiencies, are identified by the assessment team, the CRL will include those deficiencies.
Issue a CRL without facility or site deficiencies	An inspection is necessary because there is a lack of information about the facility or site but cannot be completed due to factors including travel restrictions (a facility or site deficiency will NOT be issued; the facility or site issue will be a comment in the CRL).	Other deficiencies are identified by the assessment team. The CRL will contain those deficiencies.
Defer action (i.e., miss the PDUFA date)	An inspection is necessary because there is a lack of information about a facility or site and cannot be completed due to factors including travel restrictions (a facility or site deficiency will NOT be issued).	No deficiencies have been identified, and the application otherwise satisfies the requirements for approval.

88. If the FDA sends the sponsor a CRL, the letter will describe all the specific deficiencies that the FDA identified in the NDA and when possible, recommends actions for the sponsor to take to place its NDA in condition for approval.[32] A sponsor may resubmit its NDA, responding to the deficiencies detailed

[32] Applications for FDA Approval to Market a New Drug, Complete Response Letter to Applicant, 21 C.F.R. § 314.110 (2020),

in the CRL that needed to be addressed prior to the NDA's approval.[33] Upon receipt of a resubmission, the FDA will determine whether the response is a complete response and if it is, the FDA will issue an acknowledgement letter classifying the resubmission as Class 1 or Class 2, and providing the performance goal date.[34]

89. Pursuant to PDUFA, the FDA reviews and acts on a resubmission within six months. Any resubmission starts a new review cycle – two months for a Class 1 and six months for a Class 2 resubmission – which begins when it is submitted to the FDA. This classification is based on the information submitted in response to a CRL. A Class 1 resubmission may relate to a drug's labeling, safety, stability, validation, post-marketing requirements or commitments, and/or final release testing. A Class 2 resubmission includes any item not specified in Class 1, including items warranting presentation to an advisory committee or a re-inspection.

90. As a result of the COVID-19 pandemic, the FDA made changes to the PAI process and issued multiple temporary guidances related to manufacturing,

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https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.110.

[33] CENTER FOR DRUG EVALUATION AND RESEARCH, *Manual of Policy and Procedures - Classifying Resubmissions of Original NDAs, BLAs, and Efficacy Supplements in Response to Complete Response Letters* (effective date Feb. 26, 2015), https://www.fda.gov/media/72727/download.

[34] The Class 1 or Class 2 distinction does not pertain to resubmissions of non-efficacy supplements (*i.e.* labeling and manufacturing supplements). *See* n.15.

supply chain and drug inspections during the Class Period.[35]

91. One change was implementing "an interim process to communicate issues identified following a review of records or other information requested" under § 704(a)(4) of the FD&C Act. *Id*. As part of that process, the "FDA intend[ed] to communicate issues to facility representatives following the completion of its review of records or other information requested" and "plan[ned] to consider any formal responses regarding these issues, including documentation of corrective action, prior to taking an action on a pending application impacted by these issues, as feasible given user fee agreement and internal review program milestones." *Id*.

92. In September 2020, the FDA issued industry guidance for resuming normal drug and biologics manufacturing during the COVID-19 pandemic, recommending that manufacturers identify any deviations from established cGMP activities due to COVID-19 as well as any remediation measures taken, and referred them to the previously issued March 2011 industry guidance *Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products*.[36] While the September 2020 guidance gave "examples of delayed,

[35] U.S. FOOD & DRUG ADMIN., *Manufacturing, Supply Chain, and Drug Inspections | COVID-19* (July 14, 2021) https://www.fda.gov/drugs/coronavirus-covid-19-drugs/manufacturing-supply-chain-and-drug-inspections-covid-19.

[36] U.S. FOOD & DRUG ADMIN., *Guidance for Industry - Resuming Normal Drug and Biologics Manufacturing Operations During the COVID-19 Public Health Emergency* (September 2020) https://www.fda.gov/media/142051/download.

reduced, or otherwise modified CGMP activities[,]" it confirmed that "CGMP requirements remain[ed] in effect during the COVID-19 public health emergency and …[wa]s not intended to describe FDA's enforcement priorities." *Id*.

93. At all relevant times, CorMedix's manufacturing processes were outsourced to contract facilities.[37] To select the CMO for its anticipated U.S. commercialization of DefenCath, CorMedix began the evaluation and selection process in late 2016.[38] After contacting and having initial discussions with 13 potential CMOs in the U.S. and internationally, and then conducting site visits, doing initial quality system reviews and reviewing proposals from several of those 13, the Company ultimately selected its CMO in 2017. *Id*.

94. The Class Period begins on October 16, 2019, when the Company issued a press release, later filed as Exhibit 99.1 to a Form 8-K, signed by Defendant Cook, announcing a "Successful CMC Interaction with the FDA[.]"[39] An applicant has the option to submit a complete CMC section of an NDA, 90 to 120 days before the anticipated submission of the remainder of the NDA, for early review by the

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[37] CorMedix, Inc., Quarterly Report (Form 10-Q) (Nov. 9, 2021).

[38] *See Cormedix, Inc. – Special Call*, REFINITIV STREETEVENTS (Mar. 9, 2021, 01:30PM) ("3/9/21 Call").

[39] *CorMedix Completes Successful CMC Interaction with the FDA*, GLOBENEWSWIRE. (Oct. 16, 2019), ("10/16/19 Press Release"), https://www.globenewswire.com/en/news-release/2019/10/16/1930488/0/en/CorMedix-Completes-Successful-CMC-Interaction-with-the- FDA.html.

FDA.[40] The 10/16/19 Press Release stated, in relevant part, that "[t]he FDA was supportive of Neutrolin's proposed manufacturing program, including … the container closure and testing, and indicated that it will conduct a thorough review of all the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of NDA filing" and that "[n]o further CMC meetings with FDA [we]re planned prior to NDA submission."

95. On November 14, 2019, during CorMedix's conference call with investors to discuss the earnings results for the third quarter of 2019 ("3Q19 Call"), Defendant Mounts explained:

> The manufacturing information is closely scrutinized by FDA prior to drug approval to ensure that there are no safety or efficacy [] concern[s]…Just as we have been engaged with FDA on clinical data to support safety and effectiveness of Neutrolin, we have been engaged with the [FDA] and [had] discussions on CMC information.
>
> Manufacturing of the drug product must be shown to be reproducible and reliable through validation study. Stability [a]s a product needs to be demonstrated with extensive data and subject[ed] to conditions likely to be encountered in commercial distribution to ensure the quality as a product. **As manufacturing experience expand[s], data on drug substance and drug product are generated and we s[ought] feedback from the FDA in quarter four to discuss the data that have been developed to support the NDA.** We believe that it is important to obtain guidance from FDA to ensure that we have all of the CMC information that the agency is expecting and can proactively address any question FDA may have.
>
> As we announced the press release on October 16, **FDA provided guidance on the CorMedix CMC program and indicated data that**

[40] *See* 21 CFR 314.50(d)(1)(iv).

will need to be available in the NDA for [its review].[41]

96. Defendant Armstrong also stated during the 3Q19 Call:

> The interaction with the FDA [was] on the CMC known as the chemistry manufacturing controls. As [Defendant Mounts] has indicated, is important and critical for the NDA and depending on what is requested [CorMedix] needs to assure [it] completes the work in time to not [delay] the NDA filing. As our press release of 16 October indicated the outcome of our [inter]action with the FDA was very positive. FDA was supportive of the core manufacturing processes for the drug product and the active pharmaceutical ingredients for the inclusion as part of the NDA submission.
>
> **FDA did request some additional data** which we are working to complete, so we're optimistic that the CMC module we completed a[s] plan[ned] for filing with the FDA. **FDA did indicate that it will conduct a thorough review of all of the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of the NDA review.** No further CMC meetings with FD[A] are planned prior to the NDA submission.

97. By July 8, 2020, CorMedix had completed its rolling submission for the DefenCath NDA, "despite the limitations imposed by the COVID-19 pandemic, which delayed some required laboratory testing and our submission."[42] The Company assured investors that it "has not been informed of any delays by the FDA

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[41] *CorMedix, Inc. (CRMD) CEO Khoso Baluch on Q3 2019 Results - Earnings Call Transcript*, SEEKING ALPHA (Nov. 14, 2019, 08:45 PM ET) ("3Q19 Call"), https://seekingalpha.com/article/4306874-cormedix-inc-crmd-ceo-khoso-baluch-on-q3-2019-results-earnings-call-transcript.

[42] *CorMedix Inc. Reports Submission of Defencath™ New Drug Application*, GLOBENEWSWIRE (July 8, 2020, 08:30 ET) ("7/8/20 Press Release"), https://www.globenewswire.com/en/news-release/2020/07/08/2059263/0/en/CorMedix-Inc-Reports-Submission-of-Defencath-New-Drug-Application.html.

in the review of the NDA"[43] and that in order to complete the NDA, the Company "had to work through the [CMC] information[.]"[44]

98. However, unbeknownst to investors, the Company's CMC program had been considered deficient by the FDA, the FDA had notified CorMedix of these deficiencies, and CorMedix submitted additional data in an effort to resolve the deficiencies, but such efforts were insufficient. Despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure processes were in place to assure the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards. The module containing CMC information, submitted as part of the DefenCath NDA, reflected those deficiencies. Thus, at the time of the Offering, the Company was at a substantial risk of receiving a CRL due to insufficient CMC information, delaying the NDA approval process. By the time the FDA confirmed those materialized risks, CorMedix had already benefited from its inflated share price.

2. The Offering Documents Failed to Disclose Risks Warned Of—That NDA Approval Could Be Delayed Due to Insufficient CMC

[43] CorMedix, Inc. Quarterly Report (Form 10-Q) (Aug. 10, 2020) ("2Q20 10-Q").

[44] *CorMedix Transcript CEO Khoso Baluch on Q2 2020 Results – Earnings Call*, SEEKING ALPHA (Aug. 20, 2020) ("2Q20 Call"), https://seekingalpha.com/article/4367341-cormedixs-crmd-ceo-khoso-baluch-on-q2-2020-results-earnings-call-transcript.

Information Required to Meet FDA Standards—Had Already Materialized.[45]

99. On November 11, 2020, CorMedix filed Registration Statement No. 333-249901 with the SEC (the "2020 Shelf Registration"). The 2020 Shelf Registration allowed CorMedix to offer and sell, from time to time, up to $100 million in the aggregate of any combination of the securities described therein, either individually or in units, in one or more offerings in amounts, at prices and on the terms that the Company would determine at the time of the offering (Offering). It also allowed the Company to offer common stock or preferred stock upon conversion of debt securities, common stock upon conversion of preferred stock, or common stock, preferred stock or debt securities upon the exercise of warrants.

100. The 2020 Shelf Registration became effective on November 23, 2020, and on November 27, 2020, CorMedix filed as Exhibit 1.1 to Current Report Form 8-K, signed by Defendant Baluch, the November Sales Agreement with B. Riley Securities, Inc. ("*B. Riley*") and Needham & Company, LLC ("*Needham*"). That agreement permitted *B. Riley* and *Needham* to act as the Company's agents for the sale of shares of up to $25 million of the Offering. That same day, the Prospectus Supplement for the Offering, which forms part of the Offering Documents, was filed

[45] In this Section, the alleged false and/or misleading portions of the statements are both bolded and italicized.

with the SEC (the "November 2020 Prospectus Supplement").

101. During the fiscal year ended December 31, 2020, CorMedix sold 832,676 shares of common stock under the Offering at the weighted average price of $8.69 per share, realizing net proceeds of approximately $7.0 million. On February 5, 2021, the Company allocated another $25 million of the remaining $75 million available under the Offering. Giving effect to the additional $25 million, plus the $17.8 million available as of December 31, 2020, CorMedix had a total of $42.8 million available under the Offering. During the six months ended June 30, 2021, the Company sold an aggregate of 3,737,862 shares of common stock at an average price of $11.10 per share, realizing net proceeds of approximately $41.5 million.

102. On August 12, 2021, CorMedix filed as Exhibit 1.1 to Current Report Form 8-K, signed by Defendant Baluch, the At Market Issuance Sales Agreement ("ATM Sales Agreement") with Truist Securities Inc. ("*Truist*") and JMP Securities LLC ("*JMP*"). That agreement allowed *Truist* and *JMP*, as sales agents for the Company, to sell, from time to time, an aggregate of up to $50.0 million of its common stock, pursuant to its 2020 Shelf Registration. That same day, the Company filed a Prospectus Supplement, pursuant to Rule 424(b) under the 1933 Act (the "August 2021 Prospectus Supplement"). During the six months ended June 30, 2022, the Company sold an aggregate of 3,020,340 shares at an average price of $3.78 per share, realizing net proceeds of approximately $11.42 million.

103. The November 2020 and the August 2021 Prospectus Supplements, incorporated by reference the following documents, forming part of the Offering Documents: (1) CorMedix's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 16, 2020[46]; (2) CorMedix's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, filed with the SEC on May 11, 2020[47]; (3) CorMedix's Quarterly Report for the quarter ended June 30, 2020, filed with the SEC on August 10, 2020[48]; (4) CorMedix's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 5, 2020[49]; and (5) CorMedix's Current Reports on Form 8-K, filed with the SEC on: (i) February 3, 2020; (ii) February 4, 2020; (iii) February 6, 2020; (iv) April 8, 2020; (v) April 22, 2020; (vi) April 23, 2020; (vii) May 11, 2020; (viii) July 8, 2020; (ix) July 29, 2020; (x) August 31, 2020; (xi) September 17, 2020; (xii) October 14, 2020; and (xiii) November 2, 2020.

104. On February 3, 2020, during pre-market hours, the Company issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, titled "CorMedix Inc. Announces FDA Grant of Rolling Review of Neutrolin New Drug Application" ("2/3/20 Press Release"). That press release

[46] CorMedix, Inc., Annual Report (Form 10-K) (Mar. 16, 2020) ("2019 10-K").
[47] CorMedix, Inc., Quarterly Report (Form 10-Q) (May 11, 2020) ("1Q20 10-Q").
[48] CorMedix, Inc., Quarterly Report (Form 10-Q) (Aug. 10, 2020) ("2Q20 10-Q").
[49] CorMedix, Inc., Quarterly Report (Form 10-Q) (Nov. 5, 2020) ("3Q20 10-Q").

stated, in relevant part, that "***CorMedix remains on schedule for a potential NDA approval during the second half of 2020***."[50]

105. The statement referenced in ¶104 was materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) likewise, the FDA had already raised concerns regarding the CMC information presented, including but not limited to, data sufficient to show that the labeled volume of the drug product could be consistently withdrawn from vials, despite existing in-process controls; (iii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (iv) therefore, the additional data CorMedix and its CMO were preparing to submit was insufficient to demonstrate the CMO's commercial readiness; and (v) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

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[50] *CorMedix Inc. Announces FDA Grant of Rolling Review of Neutrolin® New Drug Application*, GLOBENEWSWIRE (Feb. 3, 2020, 08:15 ET) ("2/3/20 Press Release"), https://www.globenewswire.com/news-release/2020/02/03/1978704/0/en/CorMedix-Inc-Announces-FDA-Grant-of-Rolling-Review-of-Neutrolin-New-Drug-Application.html.

106. On March 16, 2020, CorMedix filed its 2019 10-K with the SEC, signed by Defendants Baluch, Kaplan, Dillione, Dunton, Khan, and Lekfowitz. The 2019 10-K included certain "Risks Related to Dependence on Third Parties" which unbeknownst to investors, had already materialized.

107. First, the 2019 10-K warned that "***[d]ata provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading, or incomplete***." Specifically, it stated that "[w]e rely on third-party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical trials, and business. ***If such third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially adversely affected.***"

108. Second, the 2019 10-K warned that:

> Our contract manufacturers ***may not be able to comply with the applicable FDA regulatory requirements***, ***which could result in delays to our product development programs, could result in adverse regulatory actions against them or us, and could prevent us from ultimately receiving product marketing approval.*** They also generally must pass an FDA preapproval inspection for conformity with cGMPs before we can obtain approval to manufacture our product candidates and will be subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. ***If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP***, ***we may experience manufacturing errors resulting in*** defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, ***delay or prevention of filing or approval of***

> ***marketing applications for our products,*** cost overruns or other problems that could seriously harm our business. ***Not complying with FDA requirements could*** result in a product recall or ***prevent commercialization of our product candidates and delay our business development activities.*** In addition, ***such failure could be the basis for the FDA to issue a warning or untitled letter or take other regulatory or legal enforcement action, including*** recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, ***refusal to approve pending applications or supplemental applications***, and potentially civil and/or criminal penalties depending on the matter.

109. Appended as exhibits to the 2019 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein Defendant Baluch certified that "[t]he [2019 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act], as amended[,]" and that "***[t]he information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company***."

110. The statements referenced in ¶¶106-09 were materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (iii) therefore, the additional data CorMedix and its CMO were preparing to submit was

insufficient to demonstrate its commercial readiness; and (iv) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

111. On April 22, 2020, CorMedix issued a press release, later filed as Exhibit 99.1 to a Form 8-K, signed by Defendant Baluch, announcing it had completed the sale of $5.5 million of NOL tax benefits through the New Jersey Technology Business Tax Certificate Transfer Program ("4/22/20 Press Release").[51] In that press release, Defendant Baluch was quoted as stating, in relevant part "***[w]e have remained on schedule towards an anticipated approval in the second half of 2020***, subject of course to possible delays at FDA due to the coronavirus pandemic."

112. The statement referenced in ¶111 was materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) likewise, the FDA had already raised concerns to CorMedix regarding the CMC information presented, including but not limited to,

[51] *CorMedix Completes Sale of $5.5 Million of NOL Tax Benefits through New Jersey Technology Business Tax Certificate Transfer Program*, GLOBENEWSWIRE (Apr. 22, 2020, 8:00 ET) ("4/22/20 Press Release"), https://www.globenewswire.com/news-release/2020/04/22/2019921/0/en/CorMedix-Completes-Sale-of-5-5-Million-of-NOL-Tax-Benefits-through-New-Jersey-Technology-Business-Tax-Certificate-Transfer-Program.html.

data sufficient to show that the labeled volume of the drug product could be consistently withdrawn from vials, despite existing in-process controls; (iii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (iv) therefore, the additional data CorMedix and its CMO were preparing to submit was insufficient to demonstrate the CMO's commercial readiness; and (v) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

113. On May 11, 2020, the Company issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, titled "CorMedix Inc. Reports First Quarter 2020 ["1Q20"] Financial Results and Provides Business Update" ("5/11/20 Press Release").[52] That press release quoted Defendant Baluch as stating, in relevant part, that "[w]e have been working remotely since mid-March, a transition we have made with little disruption and as a result ***we are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020***."

[52] *CorMedix Inc. Reports First Quarter 2020 Financial Results and Provides Business Update*, GLOBENEWSWIRE (May 11, 2020, 1610 ET) ("5/11/20 Press Release"), https://www.globenewswire.com/en/news-release/2020/05/11/2031451/0/en/CorMedix-Inc-Reports-First-Quarter-2020-Financial-Results-and-Provides-Business-Update.html.

114. The statement referenced in ¶113 was materially false and misleading and/or omitted material facts, including that: (i) deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) likewise, the FDA had already raised concerns to CorMedix regarding the CMC information presented, including but not limited to, data sufficient to show that the labeled volume of the drug product could be consistently withdrawn from vials, despite existing in-process controls; (iii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of DefenCath were adequate to preserve its identity, strength, quality and/or purity; (iv) therefore, the additional data CorMedix and its CMO were preparing to submit was insufficient to demonstrate the CMO's commercial readiness; and (v) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

115. On July 8, 2020, during pre-market hours, CorMedix issued a press release, later filed as Exhibit 99.1 to a Form 8-K, signed by Defendant Baluch, announcing that it had completed its submission of the DefenCath NDA with the FDA for CRBSIs in patients with end-stage renal disease who are receiving hemodialysis via a central venous catheter ("7/8/20 Press Release").[53] That press

[53] 7.8.20 Press Release.

release stated, in relevant part, that "***all of the modules for the Defencath™ [NDA] have been submitted*** to the [FDA]" and that "***there has been ongoing dialogue with FDA as it reviews the submitted modules***."

116. The 7/8/20 Press Release also quoted Defendant Baluch, who represented, in relevant part, that CorMedix was "very pleased to have ***completed the submission of the NDA, despite the limitations imposed by the COVID-19 pandemic, which delayed some required laboratory testing and our submission***."

117. The statements referenced in ¶¶115-16 were materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the FDA's request for additional data reflected the existence of deficiencies at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) the required laboratory testing was likely the result of the FDA's request to CorMedix for additional information, therefore, the delayed submission is more likely a result of the foregoing deficiencies than limitations imposed by the COVID-19 pandemic; (iii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iv) the module containing CMC information, submitted as part of the DefenCath NDA, reflected those deficiencies; and (v) as a result, the DefenCath

NDA could not obtain FDA approval in the second half of 2020.

118. On August 10, 2020, CorMedix issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, reporting the Company's results for the second quarter of 2020 ("2Q20") and providing a business update (the "8/10/20 Press Release"). That press release represented, *inter alia*, that CorMedix had "***[c]ompleted the rolling submission and review of the [NDA] for Defencath to the FDA*** for the prevention of ... CRBSIs[] in patients undergoing hemodialysis via catheter."

119. Additionally, the 8/10/20 Press Release quoted Defendant Baluch, who stated, in relevant part, that "[w]e were pleased to announce ***the completion of our rolling submission for Defencath last month*** and look forward to providing updates on the acceptance for filing from FDA… We also are ***making necessary preparations for the launch of DefenCath in the U.S. hemodialysis market, following FDA approval***. We believe ***we have the team***, the focus, and a therapy that will meaningfully improve patient outcomes and are excited about the opportunities in front of us."

120. That same day, CorMedix filed a quarterly report on Form 10-Q with the SEC, reporting its financial and operating results for the quarter ended June 30, 2020, signed by Defendant Baluch. The 2Q20 10-Q discussed the Company's DefenCath NDA submission with the FDA, stating, *inter alia*, that "[i]n March 2020,

the Company began the modular submission process for the NDA for Defencath for the prevention of CRBSI in hemodialysis patients, and recently announced ***on July 8, 2020, that submission of all modules for the NDA was completed***" and that it "has not been informed of any delays by the FDA in the review of the NDA[.]"

121. Appended as exhibits to the 2Q20 10-Q were substantively the same SOX certifications referenced in ¶109, *supra*, signed by Defendants Baluch and David.

122. The statements referenced in ¶¶118-21 were materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the FDA's request for additional data reflected the existence of deficiencies at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iii) the module containing CMC information, submitted as part of the DefenCath NDA, reflected those deficiencies; and (iv) as a result, the DefenCath NDA could not obtain FDA approval.

123. On August 31, 2020, CorMedix issued a press release, later filed as Exhibit 99.1 to a Form 8-K, signed by Defendant Baluch, announcing the FDA's

acceptance for filing and priority review of the DefenCath NDA, and setting a PDUFA date of February 28, 2021, for the completion of its review ("8/31/20 Press Release").[54] That press release stated that, "[t]he FDA had previously granted a ***rolling submission and review, which the Company completed at the end of June.***"

124. The 8/31/20 Press Release also quoted Defendant Mounts, who asserted, in relevant part, that "we look forward to ***continuing to work together [with the FDA] expeditiously to complete the review of the Defencath NDA*** to address an unmet medical need."

125. The statements referenced in ¶¶123-24 were materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the FDA had already raised concerns regarding existing manufacturing records submitted as part of the NDA, and as part of its records inspection, had requested additional documents from the CMO to support its commercial readiness; (ii) deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (iii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used

[54] *CorMedix Inc. Announces FDA Acceptance for Filing and Priority Review of New Drug Application for Defencath,* GLOBENEWSWIRE (Aug. 31, 2020, 07:47 ET) ("8/31/20 Press Release"), https://www.globenewswire.com/en/news-release/2020/08/31/2086071/0/en/CorMedix-Inc-Announces-FDA-Acceptance-for-Filing-and-Priority-Review-of-New-Drug-Application-for-Defencath.html.

in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iv) the module containing CMC information, submitted as part of the DefenCath NDA, reflected those deficiencies; and (v) as a result, the DefenCath NDA could not obtain FDA approval.

126. On November 5, 2020, CorMedix issued a press release, later filed as Exhibit 99.1 to a Form 8-K, signed by Defendant Baluch, reporting the Company's results for the third quarter of 2020 ("3Q20"), and providing a business update (the "11/5/20 Press Release"). That press release represented, in relevant part, that "***CorMedix continues its interactions with the FDA regarding the … NDA[] for Defencath™*** for the prevention of ... CRBSIs[] in patients undergoing hemodialysis via central venous catheter."

127. The 11/5/20 Press Release also quoted Defendant Baluch, who stated, in relevant part, that "[w]e believe ***we have the team***, the focus, the resources, and a novel catheter lock solution that will meaningfully improve patient outcomes and are excited about the opportunities in front of us."

128. That same day, CorMedix filed a quarterly report on Form 10-Q with the SEC, reporting its financial and operating results for the quarter ended September 30, 2020 (the "3Q20 10-Q"). The 3Q20 10-Q stated, in relevant part, that:

> In March 2020, we began the modular submission process for the NDA for Defencath for the prevention of CRBSI in hemodialysis patients, and recently ***announced on July 8, 2020, that submission of all modules for the NDA was completed***. In August 2020, the FDA

> accepted for filing the Defencath NDA… ***The FDA noted that*** … ***it had not identified any potential review issues at this time…***

129. Appended as exhibits to the 3Q20 10-Q were substantively the same SOX certifications referenced in ¶109, *supra*, signed by Defendants Baluch and David.

130. The statements referenced in ¶¶126-29 were materially false and misleading because Defendants made material misstatements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the FDA had already raised concerns regarding existing manufacturing records submitted as part of the NDA, and as part of its records inspection, had requested additional documents from the CMO to support its commercial readiness; (ii) deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (iii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iv) the DefenCath NDA reflected those deficiencies; and (v) as a result, the DefenCath NDA could not obtain FDA approval.

131. By the commencement of this action, CorMedix's stock price closed at $6.42 per share on July 22, 2021, representing a 26% decline from the average $8.69 per share sold by the end of 2020 and a 42% decline from the average $11.10

per share sold in the six months ended June 30, 2021. On October 10, 2022, CorMedix securities closed at $2.85 per share, representing a 25% decline from the average $3.78 per share sold in the six months ended June 30, 2022.

B. Failure to Disclose Information Required by Items 303 and 105 of Regulation S-K

132. In addition to the materially false and misleading statements in the Offering Documents identified above, Defendants also violated their affirmative obligations to provide certain material information in the Offering Documents as required by applicable SEC rules and regulations.

133. Item 303 of SEC Regulation S-K, 17 C.F.R. § 229.303 ("Item 303"), requires the Offering Documents to "[d]escribe any known trends or uncertainties that have had or that the registrant reasonable expects will have a materially favorable and unfavorable impact on the sales or revenues or income from continuing operations."

134. In May 1989, the SEC issued an interpretive release on Item 303 ("1989 Interpretive Release"), stating, in pertinent part, as follows:

> Required disclosure is based on currently known trends, events, and uncertainties that are reasonably expected to have material effects, such as: A reduction in the registrant's product prices; erosion in the registrant's market share; changes in insurance coverage; or the likely non-renewal of a material contract.
>
> * * *
>
> A disclosure duty exists where a trend, demand, commitment,

> event or uncertainty is both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation.

135. Further, the 1989 Interpretive Release sets forth the following test to determine if disclosure under Item 303(a) is required if it is unclear whether a known trend, demand, commitment, event or uncertainty is likely to come to fruition:

> [M]anagement … must evaluate objectively the consequences of the known trend, demand, commitment, event or uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur.

136. By the Offering, the FDA had already communicated insufficiency in the CMC program presented by CorMedix for the DefenCath NDA. Thus, whether the FDA would approve the NDA based on the data and application submitted was a known uncertainty that was then having, and would continue to have, a negative impact on the Company's revenues and income from continuing operations, and was therefore, required to be disclosed in the Offering Documents but was not.

137. In addition, Item 505 of SEC Regulation S-K, 17 C.F.R. § 229.105 ("Item 105"), required, in the "Risk Factors" section of the Offering Documents, a discussion of the most significant factors that made the offering risky or speculative, and that each risk factor adequately describe the risk.

138. The Offering Documents failed to disclose that there was an increased risk that CorMedix's NDA would be denied based on deficient information because

the FDA had expressed concern regarding the data supporting the CMC program. Because this risk was not disclosed, the Director Defendants, CorMedix, Baluch, and David violated Item 105.

C. Class Action Allegations by the 1933 Act Class

139. Plaintiff brings this action as a class action pursuant to the Federal Rules of Civil Procedure ("Rules") 23(a) and 23(b)(3) on behalf of all persons who purchased CorMedix securities pursuant or traceable to the Offering pursuant to the Offering Documents. This class asserts claims only for violations of §§ 11 and 15 of the 1933 Act, 15 U.S.C. §§ 77k and 77o. This class does not assert any claims sounding in fraud. Any person who did not purchase or acquire their CorMedix shares directly in or traceable to the Offering and pursuant to the corresponding Offering Documents is not included in the 1933 Act Class. Also excluded from the 1933 Act Class are Defendants, the officers and directors of the Company, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

140. The members of the 1933 Act Class are so numerous that joinder is impracticable. The Offering involved the issuance and sale of at least 4.57 million shares of CorMedix securities, which were publicly traded on the NYSE and the NASDAQ following the sale of common stock pursuant to the Offering. While the exact number of 1933 Act Class members is unknown to Plaintiff at this time, he

believes that there are at least thousands of members in the proposed 1933 Act Class. Record owners and other members of the 1933 Act Class may be identified from records maintained by CorMedix or its transfer agents and may be notified of the pendency of this action by mail, using the form notice similar to that customarily used in securities class actions.

141. Plaintiff's claims are typical of the claims of the 1933 Act Class, as all 1933 Act Class members were and are similarly affected by Defendants' conduct.

142. Plaintiff will fairly and adequately protect the interests of the 1933 Act Class members and has retained counsel competent and experienced in securities class action litigation.

143. Common questions of law and fact exist as to all 1933 Act Class members and predominate over any questions solely affecting individual 1933 Act Class members. Among the common questions of law and fact are:

- whether Defendants violated the 1933 Act;
- whether the Offering Documents misrepresented and/or omitted material facts in violation of the 1933 Act; and
- whether and to what extent 1933 Act Class members have sustained damages and the proper measure of damages.

144. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by individual 1933 Act Class members may be relatively small, the expense and burden of individual litigation make it exceedingly difficult, if not impossible and

impracticable, for them to individually redress the alleged wrongs done to them. There will be no difficulty in managing this action as a class action.

COUNT I
Violations of § 11 of the 1933 Act
(Against the Director Defendants, CorMedix, Baluch, and David)

145. Plaintiff repeats and re-alleges the above allegations in ¶¶1-19, 35-42, 44, 58-144 as if fully set forth herein.

146. This Cause of Action is brought pursuant to § 11 of the 1933 Act, 15 U.S.C. § 77k, on behalf of the 1933 Act Class, against the Director Defendants, CorMedix, Baluch and David. This Cause of Action does not allege, and does not intend to allege, fraud or fraudulent intent, which is not a required element of § 11, and any implication of fraud or fraudulent intent is hereby expressly disclaimed.

147. Section 11 gives rise to liability to certain defendants enumerated therein if "any part of the registration statement, when such part became effective, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading. ..." 15 U.S.C. § 77k(a).

148. Among others, § 11 identifies the following categories of defendants as those who may be liable thereunder: (a) "every person who signed the registration statement"; (b) "every person who was a director of (or person performing similar functions) ... the issuer at the time of the filing of the part of the registration statement

with respect to which his liability is asserted"; (c) "every person who, with his consent, is named in the registration statement as being or about to become a director, person performing similar functions, or partner"; and (d) "every underwriter with respect to such security." 15 U.S.C. § 77k(a)(1)-(3), (5).

149. The Registration Statement, the November 2020 Prospectus Supplement, the August 2021 Prospectus Supplement, and the Company's other public filings incorporated by reference, which formed the Offering Documents for the Offering, contained inaccurate and misleading statements of material fact, omitted facts necessary to render statements therein non-misleading, and omitted to state material facts required to be stated therein.

150. CorMedix is the registrant for the Offering. Defendants named herein were responsible for the contents therein and dissemination thereof the Offering Documents, and the Director Defendants, Baluch and David each signed and/or authorized the signing of the Registration Statement or were designated therein, or in the incorporated documents, as director-nominees.

151. As the issuer of the shares, CorMedix is strictly liable to Plaintiff and the 1933 Act Class for the Offering Documents' material misstatements and omissions. Signatories of the Offering Documents and the other Defendants named herein are also strictly liable to Plaintiff and the 1933 Act Class for such material misstatements and omissions.

152. None of the Defendants named herein made a reasonable investigation or possessed reasonable grounds to believe that the statements in the Offering Documents were complete, accurate or non-misleading.

153. By reason of the conduct alleged herein, each Defendant named herein violated, and/or controlled a person who violated, § 11 of the 1933 Act.

154. Plaintiff purchased CorMedix securities pursuant to the Offering Documents.

155. Plaintiff and the 1933 Act Class have sustained damages. The value of CorMedix securities has declined substantially subsequent and due to Defendants' violations.

156. At the time of their purchases of CorMedix securities, Plaintiff and other members of the 1933 Act Class were without knowledge of the facts concerning the wrongful conduct alleged herein.

157. Less than one year elapsed from the time Plaintiff discovered, or reasonably could have discovered, the facts upon which this complaint is based to the time that Plaintiff filed this action. Less than three years have elapsed between the time that the securities upon which this Cause of Action is brought were offered to the public and the time this action was filed.

COUNT II
Violations of § 15 of the 1933 Act
(Against the Director Defendants, Baluch and David)

158. Plaintiff repeats and re-alleges the above allegations in ¶¶1-19, 35-40, 42, 44, 58-144 as if fully set forth herein.

159. This Cause of Action is brought pursuant to § 15 of the 1933 Act against the Director Defendants, Baluch and David. This Cause of Action does not allege, and does not intend to allege, fraud or fraudulent intent, which is not a required element of § 15, and any implication of fraud or fraudulent intent is hereby expressly disclaimed.

160. Where a violation of § 11 occurs, § 15 gives rise to liability as to "[e]very person who, by or through stock ownership, agency, or otherwise, or who, pursuant to or in connection with an agreement or understanding with one or more other persons by or through stock ownership, agency, or otherwise, controls any person liable under section 77k [§11..." 15 U.S.C. § 77o(a). Control persons under § 15 are "liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable[.]" *Id.*

161. As detailed herein, Baluch, David, and each Director Defendant committed primary violations of the 1933 Act, and are directly responsible and primarily liable for such violations, by committing conduct in contravention of § 11.

162. Defendants Baluch, David, and each of the Director Defendants signed

or authorized the signing and/or filing of the Offering Documents.

163. The Baluch, David, and the Director Defendants each were control persons of CorMedix by virtue of their positions as directors and/or senior officers of the Company. They each had direct and/or indirect business and/or personal relationships with other directors, officers and/or major shareholders of CorMedix. Alternatively, the Company controlled the Director Defendants, Baluch and David, given the influence and control the Company possessed and exerted over them.

164. By reason of the conduct alleged herein, these Defendants violated § 15 of the 1933 Act, resulting in harm to Plaintiff and the 1933 Act Class.

V. THE 1934 ACT CLAIMS

A. The CorMedix Defendants' Fraudulent Scheme to Hide Manufacturing Deficiencies

1. The CorMedix Defendants misled investors about the adequacy of the CMC information the Company provided to the FDA and the commercial readiness of its CMO for the U.S. market, touting its success in other markets and the strength of its team while downplaying early concerns raised by the FDA.

165. Leading up to the Class Period, CorMedix's primary focus was on ensuring its manufacturing processes and facilities met FDA standards for U.S. commercialization. The CorMedix Defendants reiterated time and time again to

investors that the Company and its team had the requisite knowledge and experience to oversee and manage the manufacture of Neutrolin (DefenCath). In August 2019, Defendant Armstrong specifically assured investors that:

> **CorMedix has been manufacturing and selling Neutrolin outside the U.S. for the last five years. We have successfully carried out technical transfer and validation of the manufacturing process, which has enabled the successful production of product at three different manufacturing sites.** This should give you comfort that we understand Neutrolin's manufacturing, technical, analytical processes as well as the quality controls and the systems that go with it. … And importantly, the key members of my staff, including me, have in our past experience, successfully submitted multiple NDAs that were ultimately approved.
>
> … Many companies, particularly small, inexperienced companies, overlook the importance of the CMC section that is required for the NDA. At CorMedix, we have not done that. **We have been diligently working and interacting with the FDA on this topic continually during the product development in the U.S.**
>
> Our press release of July 9 was an update on our ongoing discussions with FDA to ensure that all the CMC information required for the NDA will be in place. It was intended to be **a clear signal from CorMedix to life science investors that we understand the importance of manufacturing data and that we are on top of it.**
>
> In addition, we are now in the process of finalizing the supply chain and distribution network for the initial product that will be used for launch in the U.S. The initial finished product will be manufactured in Europe.[55]

166. Then, the Class Period begins on October 16, 2019 with the CorMedix

[55] *CorMedix, Inc. (CRMD) CEO Khoso Baluch on Q2 2019 Results – Earnings Call Transcript*, SEEKING ALPHA (Aug. 13, 2019, 04:30 PM ET), https://seekingalpha.com/article/4285328-cormedix-inc-crmd-ceo-khoso-baluch-on-q2-2019-results-earnings-call-transcript.

Defendants providing investors with the misleading impression that the FDA was fully on-board with CorMedix's proposed manufacturing program for DefenCath, and NDA approval would come no later than the second half of 2020.

167. Specifically, on that day, the Company declared that "[t]he FDA was supportive of Neutrolin's proposed manufacturing program…. No further CMC meetings with FDA are planned prior to NDA submission."[56] Defendant Baluch added that "Neutrolin can be approved in the second half of 2020[.]" *Id*.

168. While maintaining the false narrative of overwhelming support by the FDA, on November 14, 2019, the CorMedix Defendants informed investors that the agency had asked for additional information.[57] During CorMedix's 3Q19 Call, held on November 14, 2019, Defendant Mounts explained:

> The manufacturing information is closely scrutinized by FDA prior to drug approval to ensure that there are no safety or efficacy [] concern[s]…Just as we have been engaged with FDA on clinical data to support safety and effectiveness of Neutrolin, we have been engaged with the [FDA] and [had] discussions on CMC information.
>
> Manufacturing of the drug product must be shown to be reproducible and reliable through validation study. Stability [a]s a product needs to be demonstrated with extensive data and subject[ed] to conditions likely to be encountered in commercial distribution to ensure the quality as a product. As manufacturing experience expand[s], data on drug

[56] 10/16/19 Press Release.

[57] *CorMedix Inc. Reports Third Quarter 2019 Financial Results and Provides Business Update*, GLOBENEWSWIRE (Nov. 14, 2019, 16:05 ET), https://www.globenewswire.com/en/news-release/2019/11/14/1947574/0/en/CorMedix-Inc-Reports-Third-Quarter-2019-Financial-Results-and-Provides-Business-Update.html.

> substance and drug product are generated and we s[ought] feedback from the FDA in quarter four to discuss the data that have been developed to support the NDA. We believe that **it is important to obtain guidance from FDA to ensure that we have all of the CMC information that the agency is expecting and can proactively address any question FDA may have.**
>
> As we announced the press release on October 16, **FDA provided guidance on the CorMedix CMC program and indicated data that will need to be available in the NDA for [its review]**.[58]

169. Defendant Armstrong also stated during the 3Q19 Call:

> The interaction with the FDA [was] on the CMC known as the chemistry manufacturing controls. As [Defendant Mounts] has indicated, is important and critical for the NDA and depending on what is requested [CorMedix] needs to assure [it] completes the work in time to not [delay] the NDA filing. As our press release of 16 October indicated the outcome of our [inter]action with the FDA was very positive. **FDA was supportive of the core manufacturing processes for the drug product and the active pharmaceutical ingredients for the inclusion as part of the NDA submission**.
>
> **FDA did request some additional data** which we are working to complete, so we're optimistic that the CMC module we completed a[s] plan[ned] for filing with the FDA. **FDA did indicate that it will conduct a thorough review of all of the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of the NDA review.** No further CMC meetings with FD[A] are planned prior to the NDA submission.

170. The CorMedix Defendants' statements led investors to believe that the Company has conducted proper due diligence and quality control of the

[58] *CorMedix, Inc. (CRMD) CEO Khoso Baluch on Q3 2019 Results - Earnings Call Transcript*, SEEKING ALPHA (Nov. 14, 2019, 08:45 PM ET) ("3Q19 Call"), https://seekingalpha.com/article/4306874-cormedix-inc-crmd-ceo-khoso-baluch-on-q3-2019-results-earnings-call-transcript.

manufacturing processes and facilities utilized by its CMO contracted for commercial manufacturing in the U.S., ensuring that the CMO's facilities were cGMP-compliant and it was prepared for any type of inspection by the FDA. Further, the Company confirmed that it was "on schedule" for FDA approval in the second half of 2020, in February 2020,[59] and "maintain[ed]" this schedule, in May 2020.[60]

171. Moreover, because the CorMedix Defendants continued to tout the Company's five-year track record of successfully manufacturing and selling Neutrolin in other markets, as well as its top-notch personnel, investors believed CorMedix was well equipped and capable of satisfying regulatory standards and would have no problem providing all necessary CMC information in the DefenCath NDA. Indeed, Defendant Baluch boasted about:

> The significant experience Phoebe [Mounts] brings in regulatory, Jack [Armstrong] in manufacturing and supply chain, Paul in medical affairs and Liz in clinical operation, coupled with my Cialis and Byetta launch experience in the US just to name a few recent launches makes for a winning team. Together, we have a combined experience of over 170 years in the pharmaceutical business.

172. As the COVID-19 pandemic swept through the world in the spring of 2020, the CorMedix Defendants warned of possible delays on the side of the FDA relating to in-person inspections of foreign manufacturing facilities potentially being postponed, but declared that CorMedix and its CMO were "on track" with ensuring

[59] 2/3/20 Press Release.

[60] 5/11/20 Press Release.

the FDA had what it needed to approve the DefenCath NDA by the end of 2020:

- Baluch: "We plan to continue our filing schedule and to be on track for a decision in the second half of 2020, although we cannot at this time anticipate the impact on our timetable of the FDA's postponement of most foreign inspections." (3/16/20 Press Release)
- Mounts: "We cannot predict if this will delay approval of the NDA because pre-approval inspections of the manufacturing facilities relied upon for manufacturing of Neutrolin are required." (4Q19 Call)[61]
- Baluch: "We have remained on schedule towards an anticipated approval in the second half of 2020, subject of course to possible delays at FDA due to the coronavirus pandemic." (4/22/20 Press Release)
- Mounts: "[W]e are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020. We are all very cognizant of preparing an NDA that is complete and provides all of the information in the agency's required format to ensure an efficient review. We focused on discussions with FDA in 2019 to make sure that we understood the FDA's expectations to evaluate the manufacturing…" (1Q20 Call)
- Baluch: "[T]he effort to move the regulatory process forward with the FDA is on track. We are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020." (1Q20 Call)

173. By July 8, 2020, CorMedix had completed its rolling submission for the DefenCath NDA, "despite the limitations imposed by the COVID-19 pandemic, which delayed some required laboratory testing and our submission."[62] The

[61] *CorMedix, Inc. (CRMD) CEO Khoso Baluch on Q4 2019 Results – Earnings Call Transcript*, SEEKING ALPHA (Mar. 16, 2020, 04:30 PM ET) ("4Q19 Call"), https://seekingalpha.com/article/4332346-cormedix-inc-crmd-ceo-khoso-baluch-on-q4-2019-results-earnings-call-transcript.

[62] 7/8/20 Press Release.

Company assured investors that it "has not been informed of any delays by the FDA in the review of the NDA"[63] and that in order to complete the NDA, the Company "had to work through the [CMC] information[.]"[64]

174. Capitalizing on the Company's positive public image following the completion of its NDA submission, on July 27, 2020, CorMedix announced its plans to offer shares of its common stock in an underwritten public offering.

175. On March 9, 2018, CorMedix filed Registration Statement No. 333-223562 with the SEC. The Registration Statement (using a "shelf" registration process) allowed the Company to offer, from time to time, up to $70.0 million, any combination of the securities described therein, either individually or in units, in one or more offerings in amounts, at prices and on the terms that the Company would determine at the time of the offering. On April 16, 2018, the Prospectus for the Registration Statement, became effective.

176. On July 28, 2020, the Company filed with the SEC, the Prospectus Supplement for the public offering announced on July 27, 2020. Thereafter, CorMedix offered and sold 5,111,110 shares of common stock, which included the exercise by the underwriters of their option to purchase additional shares, at a public

[63] 2Q20 10-Q.

[64] *CorMedix Transcript CEO Khoso Baluch on Q2 2020 Results – Earnings Call*, (Aug. 20, 2020) ("2Q20 Call"), https://seekingalpha.com/article/4367341-cormedixs-crmd-ceo-khoso-baluch-on-q2-2020-results-earnings-call-transcript.

offering price of $4.50 per share for gross proceeds of approximately $23.0 million.

177. As the FDA continued its review of the DefenCath NDA, CorMedix further informed investors that it was working closely with the agency and was not being told of any issues related to its submission or the FDA's review. For example, on August 31, 2020, when announcing the FDA's acceptance of the NDA for priority review and setting a February 28, 2021 PDUFA date, CorMedix "noted that [the FDA] … had not identified any potential review issues at this time."[65] The Company maintained the same messaging on November 5, 2020 in reporting its 3Q20 financial results, simply warning that it "has not been informed of any delays by the FDA in the review of the NDA, but … pre-approval inspections are required for manufacturing sites."[66]

178. To investors then, the FDA review of the DefenCath NDA (including the manufacturing information) appeared to be going well. Particularly when, on November 18, 2020, CorMedix announced it "has been notified that based on the [FDA]'s ongoing dialogue with the Company, discussion at an advisory committee is not needed, and it will continue to work on the application with CorMedix during the remainder of the review cycle."[67] At the same time, Defendant Baluch assured

[65] 8/31/20 Press Release.

[66] 3Q20 10-Q.

[67] *CorMedix Inc. Announces FDA Decision That Advisory Committee Meeting for*

investors of the high "level of engagement between FDA and the CorMedix team during the NDA review process" and Defendant Mounts confirmed the team's "continu[ed] effort and dialogue with the [FDA] to ensure that the priority review process can be completed expeditiously." *Id*. On these statements, CorMedix's share price rose over 11%.

179. Capitalizing on the continued artificial price of its securities, on November 27, 2020, CorMedix announced the completion of its November Sales Agreement, and filed its November 2020 Prospectus Supplement for the Offering. During 2020, the Company sold 832,676 shares of common stock under the Offering at a weighted average price of $8.69 per share, realizing net proceeds of approximately $7.0 million, and during the first six months ended 2021, the Company sold an aggregate of 3,737,862 shares of common stock at an average price of $11.10 per share, realizing net proceeds of approximately $41.5 million.

180. While the CorMedix Defendants mentioned the request of additional information by the FDA during the Company's October 2019 CMC meeting, at no point did they reveal the severity of those concerns. Nor did they inform investors

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New Drug Application for Defencath is Not Needed, GLOBENEWSWIRE (Nov. 18, 2020, 08:30 ET), ("11/18/20 Press Release"), https://www.globenewswire.com/en/news-release/2020/11/18/2129199/0/en/CorMedix-Inc-Announces-FDA-Decision-That-Advisory-Committee-Meeting-for-New-Drug-Application-for-Defencath-is-Not-Needed.html.

that the request for additional information was based on identified deficiencies in the manufacturing process, in addition, to mounting deficiencies at the CMO's manufacturing facilities. Because the CorMedix Defendants failed to ensure that the Company's CMO was, and remained, cGMP-compliant throughout the collection of information for the submission of the DefenCath NDA and the FDA's review process, the agency observed numerous deficiencies relating to the CMO's facilities and the CMC information provided by the Company.

181. Investors were therefore shocked when, before markets opened on March 1, 2021, instead of announcing FDA approval, CorMedix disclosed receipt of the FDA's First CRL, declining approval of the NDA in its present form.[68] The Company explained that the "FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility" and "is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials." *Id*. On this news, CorMedix's stock price fell 54.4%, or $8.16, to close at $6.84 on March 3.

2. <u>After the First CRL, the CorMedix Defendants doubled down on their false narrative that the Company was on track to resolve the manufacturing deficiencies identified by the FDA and resubmit the DefenCath NDA in 2021.</u>

[68] 3/1/21 Press Release.

182. Unbeknownst to its investors, however, CorMedix had failed to give a complete picture of what was in the First CRL and continued to downplay its level of involvement and responsibility in the manufacturing process of DefenCath. This is a common practice for drug sponsors that receive CRLs. A cross-sectional study published in April 2015 comparing the content of CRLs and the drug sponsor's associated public announcements found that when press releases were issued, they omitted most of the statements in the CRLs.[69] In the press releases analyzed, only 14% of the deficiencies cited by the FDA were noted in the announcement. *Id*. The study concluded that "[p]ress releases are incomplete substitutes for the detailed information contained in [CRLs]." *Id*.

183. In addition to limiting the information disclosed in the First CRL, the CorMedix Defendants knew they still had damage control to do. As analyst Joon Lee of *Truist* noted on March 1, 2021, "CRMD disclosed this AM it has received CRL due to third party manufacturing issues without disclosing the nature of the issue. ***This comes as a surprise as the product has already been in production and***

[69] Comparison of content of FDA letters not approving applications for new drugs and associated public announcements from sponsors: cross sectional study. *Compare* Asher Mullard, *Sponsors rarely disclose Refuse to File letters, finds study of regulatory transparency gap in* Nature Reviews – Drug Discovery (Vol. 20, Apr. 2021) and, Peter Lurie, Harinder S. Chahal, Daniel W. Sigelman, Sylvie Stacy, Joshua Sclar, Barbara Ddamulira, *Comparison of content of FDA letters not approving applications for new drugs and associated public announcements from sponsors: cross sectional study*, BMJ 2015;350:h2758 (Apr. 8, 2015).

commercial in the EU, albeit at limited capacity." (Emphasis in original).[70]

184. The CorMedix Defendants immediately spoke with Mr. Lee, giving him enough assurances to issue another analyst report that day – one that emphasized that "today's 40% selloff appears overdone" ("3/1/21 *Truist* Report").[71] With regard to the "manual extraction study[,]" the report specifically explained that:

> [M]gmnt stated that the vials contain an 'overage' to ensure that labeled volume can be extracted…. It appears to be a routine process and believes a separate study is unlikely to be needed as long as company can convince that FDA that the 'overage' included is sufficient to enable extracting of labeled volume.

185. At the same time, the 3/1/21 *Truist* Report confirmed that CorMedix's "Mgmnt was aware that the FDA has requested additional information from the EU based third party manufacturer." *Id.* But Defendants had chosen not to provide investors with this material information earlier, keeping investors in the dark about known concerns raised by the FDA.

186. Thus, despite being forced to disclose manufacturing deficiencies as a result of the First CRL, the CorMedix Defendants tried to soften the blow by slowly releasing disappointing information, intermixed with reinforcements of the Company's management and its CMO's ability to achieve commercialization in the

[70] Joon Lee, M.D., Ph.D., Les Sulewski, *CRL Due to CMC Issues. No Deficiencies Related to Efficacy or Safety of Defencath*, TRUIST SECURITIES (Mar. 1, 2021).

[71] Joon Lee, M.D., Ph.D., Les Sulewski, *Selloff on CMC Issues Overdone. REIT BUY But PT To $30 (-$5) On Launch Delays*, TRUIST SECURITIES (Mar. 1, 2021).

U.S. For example, based on his conversation with the Company's management, Mr. Lee issued yet another analyst report on March 2, 2021 titled "Additional Color from Management on Contract Manufacturer in Question[.]"[72] That report provided that CorMedix "management reiterated that the CMO manufactures drugs sold in the U.S.[,] implying some level of FDA inspection in the past that passed FDA's standards" and "alluded that the CMO is experienced in handling drug/device combos similar in scope to Defencath." *Id.*

187. On March 9, 2021, during pre-market hours, CorMedix hosted a special conference call to provide additional color on the FDA's review process, the manufacturing deficiencies identified by the FDA, resulting in the First CRL, and the Company's ongoing collaboration with its CMO to try and address these defeciencies (the "CRL Call"). During that call, Defendant Baluch confirmed that:

> [W]e have received the FDA communication regarding our third-party manufacturing facility and we have been in extensive discussions with the CMO, with the goal of better understanding all of the information submitted to the FDA and the deficiencies identified by the FDA.
>
> We've also been jointly working on draft responses and planned activities to resolve each of the items identified.
>
> The timeline we outlined from our March 1, 2021, press release for a planned meeting with the FDA of mid-April is still valid based on our current understanding and the progress that we have made to date.

[72] Joon Lee, M.D., Ph.D., Les Sulewski, *Additional Color from Management on Contract Manufacturer in Question*, TRUIST SECURITIES (Mar. 2, 2021) ("3/2/21 Trist Report").

188. Defendant Mounts also stated during the CRL Call, in relevant part:

> FDA did not approve the new drug application for DEFENCATH and instead issued a complete response letter because it concluded that the manufacturing facility is not ready to support commercial operations for DEFENCATH. This conclusion was based on a review of records requested by FDA from the CMO…. **FDA began requesting documents from the CMO for a records assessment without doing an on-site inspection and followed up with additional requests to the CMO in the subsequent months. We were also responding to FDA with questions from the review of manufacturing records that CorMedix had submitted in the NDA.**

189. In addition, during the CRL Call, Defendant Armstrong stated, in relevant part, "**Consistent with industry practice, we continued to work closely with the CMO via site visits and regular conference calls to prepare for an FDA inspection after submission of the NDA**."

190. Defendant Armstrong also added, in relevant part:

> [T]he process CorMedix followed in selecting our drug product CMO. We began the evaluation and selection process in late 2016 because of the long lead time. We had several criteria in the selection process: quality system, capacity and cost. We contacted and had initial discussions with 13 potential CMOs in the U.S. and internationally. After the initial assessments, we narrowed the list of several, including U.S. and international sites for more detailed assessment. We then conducted site visits, did an initial quality system review, reviewed proposals and ultimately selected our CMO in 2017. **We followed the industry standard practice of executing a manufacturing agreement, quality agreement and development of a project plan for technical, analytical transfer and validation with the associated documentation**. Thereafter, we proceeded to execute on the project plan, which included an engineering batch and 3 commercial scale drug product validation batches. *Id.*

191. During the Question-and-Answer ("Q&A") Session of the CRL Call, Defendant Mounts stated, in relevant part:

> **I can confirm that the fill lines are solely for DEFENCATH.** So they're not used for any other product manufacture. As you can imagine, a lot of the information involved in filling lines is proprietary to the facility. **And as you will likely expect, there is a confidentiality agreement in place to protect that information. So I cannot disclose any more specific information about the vial filling line.**

192. The CorMedix Defendants knew or should have known about the deficiencies in the process for withdrawing the labeled volume from vials since before the Class Period when the Company was having CMC discussions with the FDA. The CorMedix Defendants knew about or recklessly ignored the new equipment being installed at the CMO's facility for another drug product since at least its July 2020 public announcement (*see* § V.A.3.). Since the CMO manufactured multiple different drug products, the CorMedix Defendants also knew or recklessly ignored that they needed to ensure that its protocols relating to changeover of manufacturing lines and visual inspections of drug products met cGMP standards and that deficient protocols relating to changeover of manufacturing lines and visual inspections of drug products could and would cause contaminated vials, which would delay the CMO's ability to obtain the data requested by the FDA relating to the qualification of the filling operation.

193. During the CRL Call, the CorMedix Defendants also made statements downplaying the issues underlying the First CRL and confirming that the

Company's personnel had the skills and experience to successfully resolve the issues, including, *inter alia*:

- Mounts: "Based on our discussions with the CMO, we believe these deficiencies can be resolved in the coming weeks."
- Mounts: "For example, one deficiency results from the proposed future installation of new equipment, but it was apparently not clear to FDA that ***the equipment is unrelated to the manufacturer of DEFENCATH*** because FDA has requested details to assess the impact to production readiness for DEFENCATH."
- Mounts: "***We have submitted data to FDA to demonstrate performance with the specifications but we intend to conduct the requested manual extraction study and expect it to be completed in the next several weeks.***"
- Mounts: "Another deficiency identifies concerns an ***airflow visualization study***, and will likely necessitate repeating the study to demonstrate adequate dynamic conditions in the study, which we believe ***can be accomplished in the next several weeks***."
- Baluch: We believe we have within CorMedix and the CMO, the resources and capabilities to achieve successful resolution of the manufacturing deficiencies to the satisfaction of the FDA.[73]

194. Based on these and other statements during the CRL Call, industry analysts following CorMedix believed the manufacturing deficiencies underlying the First CRL were manageable and would be resolved within weeks:

- *JMP*: "Based on the details provided on this morning's conference call, we believe the manufacturing issues are straightforward and can be resolved within weeks."[74]

[73] 3/9/21 Call.

[74] Jason N. Butler, PhD, Roy Buchanan, PhD. *Details on Defencath Manufacturing CRL Issues Support Potential for Rapid Resolution*, JMP SECURITIES LLC ("JMP") (Mar. 9, 2021).

- *Truist*: "Update Suggest Fixes Are Manageable."[75]
- *Wainwright*: "We did not hear anything on yesterday's call that in our view justifies heightened concern… ."[76]

195. The Company maintained the same messaging on March 30, 2021, during its fourth quarter and full year 2020 ("4Q20") earnings conference call with analysts and investors[77]:

- Baluch: "[W]e have ***the right team*** and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified."
- Mounts: "The timeline we outlined on March 1 and reiterated on March 9 for a planned meeting with the FDA in mid-April remains ***on track*** based on the progress we have made."
- Mounts: "We make sure that we -- where we could, ***we provided information that was responsive*** to the deficiency."
- Mounts: "[T]he issue was planned expansion at the manufacturing facility, which involved installation of new equipment. That is new equipment non-intended for manufacturer of DEFENCATH. So, ***the information that has been used and is in place is the appropriate equipment*** for DEFENCATH manufacture."

196. Based on these and other statements made by the Company on March 30, 2021, industry analysts continued to believe that CorMedix would resolve the

[75] Joon Lee, M.D., Ph.D., Les Sulewski, *Update Suggest Fixes Are Manageable. More To Follow*, TRUIST SECURITIES, INC. (Mar. 9, 2021).

[76] Raghuram Selvaraju, Ph.D., *Update Conference Call Clarifies Regulatory Situation; Reiterate Buy*, H.C. WAINWRIGHT & CO, LLC ("Wainwright") (Mar. 10, 2021).

[77] *CorMedix Inc. (CRMD) CEO Khoso Baluch on Q4 2020 Results – Earnings Call Transcript*, SEEKING ALPHA (Mar. 30, 2021, 06:10 PM ET) ("4Q20 Call"), https://seekingalpha.com/article/4416889-cormedix-inc-crmd-ceo-khoso-baluch-on-q4-2020-results-earnings-call-transcript.

manufacturing deficiencies and resubmit its NDA in May 2021:

- "[O]ur enthusiasm for Defencath remains unchanged, especially in light of no issues found with the drug during the FDA review."[78]
- "[B]ased on mgmnt commentaries, our base case is that CMC issues can be resolved expeditiously without the need for an FDA site visit. We look forward to updates from the mid-April FDA meeting."
- "The company remains on track to meet with the FDA regarding the manufacturing CRL for Defencath in mid-April. We remain of the view … that the deficiencies can be quickly resolved, supporting an NDA resubmission in May."[79]
- "Management commented that it did include new information to address FDA's questions in the meeting request package, further reinforcing our view that the [First] CRL can be quickly resolved and the NDA submitted in May."

197. On the same call, a *Truist* analyst observed: "[T]he impression is that it was the [CMO's] deficiencies, so what are you -- why do you need to be involved in addressing their issues? What is it that you can contribute to the CMO's deficiencies?" In response, Defendant Mounts advised:

> I think folks don't understand that there's a parallel process here. As you noted, **we have direct control over documentation and information on manufacturing, that's submitted directly to the new drug application.** As part of that process, FDA inspects the manufacturing facility and reviews documentation and the facility for its ability to manufacture that product in a commercial setting.
>
> **So the inspection by FDA**, whether it's by records assessment or an on- site inspection, **involves reviewing manufacturing records**

[69] Joon Lee, M.D., Ph.D.Les Sulewski, *Our Enthusiasm for Defencath Remains Unchanged Despite Cash Overhang and Regulatory Uncertainty*, TRUIST SECURITIES, INC. (Mar. 30, 2021)

[79] Jason N. Butler, PhD, Roy Buchanan, PhD, *4Q20: Update: On the Offensive for Defencath in 2021*, JMP SECURITIES LLC (Mar. 31, 2021).

> **for the product in the NDA, but it also goes broader than that. It goes to the actual facility and the equipment to the maintenance and the training and the personnel.**
>
> So, it's a parallel process, but obviously they are intertwined and can't be separated, because **FDA is there to look at the potential for that facility to manufacture the product that's the subject of the NDA.**

198. However, this enthusiasm was short-lived, when on April 14, 2021, CorMedix announced, representatives from both the Company and its CMO had met with FDA to discuss proposed resolutions for the deficiencies identified in the First CRL and the corresponding Post-Application Action Letter ("PAAL") received by the CMO.[80] That day, the Company was forced to disclose that to meet the FDA's requirements for the manufacturing process of DefenCath, it would have to take more remedial steps than previously identified. As a result, the Company's NDA resubmission would not occur in May 2021.

199. On this news, the Company's stock price fell over 18%. As analysts following CorMedix noted, "[i]nvestors appear to be responding negatively to the [C]ompany announcing today that it has met with the [FDA] to discuss proposed resolutions for the deficiencies identified in the [First CRL] to CorMedix and the Post-Application Action Letter received by the third-party manufacturer (CMO)

[80] *CorMedix Has Meeting With FDA on DefenCath Catheter Lock Solution NDA*, GLOBENEWSWIRE (Apr. 14, 2021, 09:00 ET) ("4/14/21 Press Release"), https://www.globenewswire.com/news-release/2021/04/14/2210054/0/en/CorMedix-Has-Meeting-With-FDA-on-DefenCath-Catheter-Lock-Solution-NDA.html.

from FDA for the [NDA] for DefenCath[.]"[81]

200. The 4/14/21 Press Release did, however, provide some assurances regarding the Company's path forward to resubmission. Specifically, the CorMedix Defendants assured investors "[t]here [wa]s now an agreed upon protocol for the manual extraction study identified in the [First] CRL", which CorMedix expected to complete "in the next several weeks." In addition, the CorMedix Defendants stressed that "CorMedix and the CMO continue to work closely to ensure that the identified deficiencies are resolved prior to resubmission of the DefenCath NDA." Industry analysts were thus calmed by the promise of approval before the end of 2021:

- "We are confident that there is a clear resolution plan agreed upon with the FDA to address the manufacturing CRL… The company and its CMO will complete all of the necessary items to resolve the [First] CRL prior to the resubmission… We are maintaining our base-case view for the launch of Defencath in 4Q21."[82]
- "Based on today's update we anticipate NDA resubmission in the next few months by around 3Q21 followed by FDA decision on the need for a site visit sometime in late 3Q21 or 4Q21[.]"[83]

201. Also on April 14, 2021, the FDA provided new guidance for remote

[81] Amit Chowdhry, *CRMD Stock: Over 10% Decrease Intraday Explanation*, PULSE 2.0 (Apr. 14, 2021) https://pulse2.com/crmd-stock-nasdaq-cormedix-over-10-decrease-intraday-explanation/.

[82] Jason N. Butler, PhD, Roy Buchanan, PhD, *Post-FDA-Meeting Update for Defencath*, JMP SECURITIES LLC (Apr. 14, 2021).

[83] Joon Lee, M.D., Ph.D., Les Sulewski, *CRMD Met With The FDA. Need For Site Visit To Be Determined Post NDA Resubmission*, TRUIST SECURITIES, INC. (Apr. 14, 2021).

evaluations of drug manufacturing site evaluations to accommodate the challenges of physical site visits during the ongoing pandemic.[84] After speaking to Defendants about this new guidance, *Truist* analyst Lee noted that "[w]e spoke to management this morning on this document. Management believes it certainly opens the door for a virtual visit as opposed to a physical on-site visit…We still believe resubmission is likely in 3Q21 with FDA update in 4Q21."[85]

202. Yet after markets closed on May 13, 2021, investors were surprised to learn that "additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA," preventing CorMedix from being able to resubmit its NDA until 4Q21, eliminating any hopes of approval before the end of 2021.[86] On this news, its stock price fell nearly 20%.

203. The CorMedix Defendants still, however, touted the Company's ability to resolve the manufacturing deficiencies and resubmit its NDA by the end

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[84] U.S. FOOD & DRUG ADMIN., *FDA Provides Guidance on Remote Interactive Evaluations for Oversight of Drug Facilities During COVID-19* (Apr. 14, 2021), https://www.fda.gov/news-events/press-announcements/fda-provides-guidance-remote-interactive-evaluations-oversight-drug-facilities-during-covid-19.

[85] Joon Lee, M.D., Ph.D., Les Sulewski, *Path to Remote Virtual Inspection Appears Feasible Based on Recent FDA Guidance*, TRUIST SECURITIES, INC. (Apr. 15, 2021).

[86] *CorMedix Inc. Reports First Quarter 2021 Financial Results and Provides Business Update*, GLOBENEWSWIRE (May 13, 2021 16:01 ET) ("5/13/21 Press Release"), https://www.globenewswire.com/news-release/2021/05/13/2229438/0/en/CorMedix-Inc-Reports-First-Quarter-2021-Financial-Results-and-Provides-Business-Update.html.

of the year:

- 5/13/21 Press Release: "[W]e have ***the right team*** and resources to accomplish this as we advance DefenCath through the regulatory approval process." (Baluch)
- 1Q21 10-Q: "***The Company and the CMO continue to work closely*** to ensure that the identified deficiencies are resolved prior to resubmission of the DefenCath NDA."
- 1Q21 Call: "[W]e have ***the right team*** and appropriate resources in place to resolve the third-party manufacturing deficiency."
- 8/12/21 Press Release: "CorMedix … remains ***on schedule*** to re-submit the DefenCath™ [NDA] in [4Q21]." (Baluch)[87]
- 2Q21 Call: "[W]e are ***on schedule*** to be able to resubmit the CorMedix NDA in quarter 4, 2021. … We remain confident that we have ***the right team*** and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified[.]" (Baluch)[88]
- 2Q21 Call: "[W]e remain ***on schedule*** to resubmit the … NDA in [4Q21]. … [W]e are ***working closely with the[CMO] and CMC consultants engaged by CorMedix*** to ensure that we are addressing FDA concerns appropriately." (Mounts)

204. During the Company's 2Q21 Call, held on August 12, 2021, *Needham* analyst Chad Messer, asked:

Just wondering about the potential for FDA inspection. I know you

[87] *CorMedix Inc. Reports Second Quarter and Six Month 2021 Financial Results and Provides Business Update*, GLOBENEWSWIRE (Aug. 12, 2021 16:01 ET) ("8/12/21 Press Release"), https://www.globenewswire.com/news-release/2021/08/12/2280058/0/en/CorMedix-Inc-Reports-Second-Quarter-and-Six-Month-2021-Financial-Results-and-Provides-Business-Update.html.

[88] *CorMedix Inc. (CRMD) CEO Khoso Baluch on Q2 2021 Results – Earnings Call Transcript*, *SEEKING ALPHA* (Aug. 12, 2021) ("2Q21 Call"), https://seekingalpha.com/article/4448910-cormedix-inc-crmd-ceo-khoso-baluch-on-q2-2021-results-earnings-call-transcript.

> guys are hoping -- you don't get one but want to be prepared for one or at least make sure you're -- you do everything you can that your third-party manufacturer is prepared to if you get one. Is it possible for you to give us a little bit of sort of historical perspective on what kind of issues we may or may not have to have to deal with inspection like that?

205. In an effort to qualm any concerns of preparedness or knowledge of what to expect during FDA inspections, Defendant Mounts acknowledged that she had reviewed the FDA database of warning letters from other inspections, and as a result, the areas in which the FDA may have concerns were "obvious" to her:

> There's an abundance of information in FDA database from warning letters, where FDA has gotten and inspected manufacturing facilities. **So it's obvious the kinds of things that the agency looks for when it does an inspection.** So that certainly can provide you with this historical perspective.

206. Thus, industry analysts (and investors) still believed the CorMedix Defendants, particularly because they gave the impression they were intimately involved in resolving the manufacturing deficiencies rather than just leaving it to the CMO:

- "Most importantly, the company is making good progress toward resubmission of the Defencath NDA, including completion of the manual extraction study. The company is advancing process qualification and validation activities, based on which it now expects to resubmit the Defencath NDA in 4Q21. … Additionally, this morning the company appointed a Chief Commercial Officer with deep experience and demonstrated success in the renal disease space."[89]
- "Company remains on track to submit NDA in 4Q21. …[T]he

[89] Jason N. Butler, PhD, Roy Buchanan, PhD, *1Q21 Update: Diligently Advancing to the Defencath NDA Re-Submission*, JMP SECURITIES LLC (Apr. 14, 2021).

process qualification of vial filling process appears to be in progress by the CMO with inputs from CRMD and outside consultant. The new batches manufactured for these studies will need to undergo new stability tests but mgmnt state that it will not be a rate limiting step to ultimate approvability of DefenCath."[90]

- "The most important update from the quarter was that CorMedix affirmed it remains on track to resubmit in 4Q21 the Defencath NDA for the prevention of catheter-related bloodstream infections."[91]
- "The remaining process qualification and validation work requested by FDA is being completed by the third-party facility, in close collaboration with the CMC and regulatory teams of CorMedix and CMC consultants. CorMedix management affirmed that it remains in agreement with the third-party manufacturer on the appropriate steps to resolve the FDA's concerns. CorMedix is also working with the manufacturing facility to prepare for a potential on-site or remote inspection by the FDA." *Id.*

207. Capitalizing on the continued artificial price of its securities, on August 12, 2021 CorMedix announced the completion of its ATM Sales Agreement with *Truist* and *JMP*, as sales agents, pursuant to which the Company could sell, from time to time, an aggregate of up to $50 million of its common stock, which was the remaining balance of the 2020 Shelf Registration.[92] The Company filed its August 2021 Prospectus Supplement for the Offering that same day.[93] During the six months ended June 30, 2022, the Company sold an aggregate of 3,020,340 shares

[90] Joon Lee, M.D., Ph.D., Les Sulewski, *DefenCath Remains on Track for NDA Resubmission 4Q21. Reit BUY*, TRUIST SECURITIES, INC. (Aug. 12, 2021).

[91] Jason N. Butler, PhD, Roy Buchanan, PhD, *2Q21 Update: On Track for Defencath NDA Resubmission in 4Q21*, JMP SECURITIES LLC (Aug. 13, 2021).

[92] 2021.08.12 8-K.

[93] 2021.08.12 Prospectus Supplement, No. 333-249901

and realized net proceeds of $11,415,000.[94]

208. Then on September 7, 2021, during pre-market hours, the Company once again shocked investors revealing that it "ha[d] encountered delays at its third-party" manufacturing facility and "the timeline for CorMedix and the CMO to address deficiencies at the facility that are required for resubmission of the DefenCath NDA [wa]s uncertain[.]"[95] In other words, the "CMO delay br[ought] uncertainty to Defencath NDA resubmission timelines[.]"[96] On this news, CorMedix's stock price fell over 27%.

209. Securities analysts recognized that investors had reacted negatively to the continued unresolved manufacturing deficiencies which were delaying the Company's NDA resubmission.

- CorMedix "slumps 20.6% premarket after the company provided an update with respect to its resubmission timeline for the DefenCath [NDA]."[97]

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[94] 2022.08.12 2Q22 10-Q.

[95] *CorMedix Inc. Announces Regulatory Update*, GLOBENEWSWIRE (Sept. 7, 2021, 08:30 ET) ("9/7/21 Press Release"), https://www.globenewswire.com/news-release/2021/09/07/2292524/0/en/CorMedix-Inc-Announces-Regulatory-Update.html.

[96] Jason N. Butler, PhD, Roy Buchanan, PhD, *Defencath Announcement Increases Timing Uncertainty, but Fundamental Impact Unlikely*, JMP SECURITIES LLC (Sept. 7, 2021).

[97] Mamta Mayani, *CorMedix plummets 21% after facing delays at contract manufacturer*, SEEKING ALPHA (Sept. 7, 2021, 09:15 AM ET) ("9/7/21 Seeking Alpha"), https://seekingalpha.com/news/3737518-cormedix-plummets-24-after-facing-delays-at-contract-manufacturer.

- CorMedix's "stock was getting crushed on Tuesday, with shares down 23.7% as of 11 a.m. EDT … after the company announced that it 'has encountered delays at its third-party contract manufacturer.' These delays will push back CorMedix's refiling for [FDA] approval of its DefenCath antibacterial and antifungal catheter lock solution by an undetermined amount of time."[98]

210. Moreover, the continued delays in resolving the manufacturing deficiencies, resulting in the First CRL, and subsequent delayed resubmission of the DefenCath NDA, indicated that the Company did not have the "right team" to achieve commercialization in the U.S., as confirmed on October 4, 2021.[99] That day, CorMedix announced that, effective immediately, Defendant Baluch was retiring from his role as CEO and resigning from the Company's Board (after being "at the helm" for over five years), and Defendant Armstrong was retiring from CorMedix with Defendant Mounts taking over the Company's "technical operations group, including a group of consultants that are working on addressing the situation with the CMO."[100]

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[98] Keith Speights, *Why CorMedix Stock Is Getting Crushed Today*, THE MOTLEY FOOL (Sept. 7, 2021, 11:20 AM) ("9/7/21 Motley Fool"), https://www.fool.com/investing/2021/09/07/why-cormedix-stock-is-getting-crushed-today/.

[99] *CorMedix Inc. Announces Executive Leadership Changes*, CORMEDIX, INC. (Oct. 4, 2021), https://www.cormedix.com/cormedix-inc-announces-executive-leadership-changes/.

[100] Joseph Sullivan, *A month after a manufacturing hiccup led to a CRL, CorMedix CEO will retire*, ENDPOINTS NEWS (Oct. 5, 2021, 07:20 AM EDT) https://endpts.com/a-month-after-a-manufacturing-hiccup-led-to-a-crl-cormedix-ceo-will-retire/.

211. Then, on November 9, 2021, during the Q&A Session of the 3Q21 Call, in response to a pre-submitted written question, which recalled that "CorMedix referred to specialized consultants in a recent press release[,]" and asked "how they [we]re assisting the company with the resubmission process[,]" Defendant Mounts confirmed that CorMedix did not have the "right team" stating, in relevant part:

> ***Obviously, we have CorMedix specialists, but because of the importance of these activities*** and the need to have everything done as quickly as possible, ***we have engaged the team of external consultants to provide additional expertise on FDA's expectations for addressing the specific deficiencies at the manufacturing facility, and to assist in preparations for a pre-approval inspection***.
>
> So, ***we wanted to make sure that we had adequate resources and sufficient knowledge of what FDA will be looking for*** to make sure that we were being comprehensive and complete in all of our activities.

3. Despite reassurances that all manufacturing deficiencies had been resolved, CorMedix received a Second CRL for the same non-compliant CMO – and for a non-compliant API manufacturer.

212. Despite the delays and leadership changes, the market remained hopeful of the Company's ability to achieve FDA approval for DefenCath, largely in part because, the CorMedix Defendants' statements for the remainder of the Class Period provided the false impression that they were turning a corner and were making strides in collecting all necessary data and information that the Company *and* its CMO had to provide the FDA to address the identified manufacturing deficiencies. Indeed, investors were misled into believing that the CorMedix

Defendants had made necessary improvements to its management and oversight of the Company's manufacturing processes and contracting facilities, and that once all corrective actions were completed and the NDA resubmitted, there was no risk of CorMedix receiving anything other than FDA approval.

213. In reporting its 3Q21 financial results on November 9, 2021, CorMedix confirmed it was still working on "address[ing] the deficiencies identified at the manufacturing facility."[101] Likewise, during the 3Q21 earnings conference call, Defendant Mounts specifically noted that:

> As noted by Matt [David], and as we disclosed in early September, there was a delay as a result of issues that the CMO that were unrelated to the manufacture of DEFENCATH. We have been able to resume manufacturing activities and are continuing to complete the work that is required to address the deficiencies identified by the FDA.
>
> Specifically, we have discussed previously that FDA had identified deficiencies involving activities associated with the vial filling line for DEFENCATH at the CMO, in particular, to target filling up volumes.
>
> After analyzing available data, parameters of the filling operation were adjusted, and we determined that qualification of the filling operation was required. It will require some time to complete testing and preparation of documentation to resubmit the manufacturing module of the new drug application or NDA for DEFENCATH.
>
> Until we have completed all of the testing, we will not be able to

[101] *Cormedix Inc. Reports Third Quarter 2021 Financial Results And Provides Business Update*, CORMEDIX, INC. (Nov. 9, 2021), https://www.cormedix.com/cormedix-inc-reports-third-quarter-2021-financial-results-and-provides-business-update/.

give specific guidance regarding the timing of resubmission.[102]

214. In addition, during the Q&A Session of the 3Q21 Call, Defendant Phoebe explained that:

> The vial filling activities that we're currently undertaking involve manufacturing of DEFENCATH and it's during that process that we are doing the testing that FDA requires to demonstrate that the process is in fact qualified. So, it's a validation process that's ongoing that actually requires the manufacturing activities, which is why when there was a delay, we had a problem in doing the manufacturing.
>
> So, now that the manufacturing has resumed, we can continue generating the data and the documentation that we need to submit to FDA. And the new batches are part of that process. So, obviously, we're manufacturing batches as we go and analyzing those batches to collect the data and can generate documentation.

215. One analyst noted that a key takeaway from the 3Q21 Call was the fact that "CorMedix and its CMO ha[d] now resumed manufacturing activities to address the [First] CRL and [we]re advancing towards resubmission of the DefenCath NDA."[103] Further, *JMP* analysts professed that they "again confirmed that there remain[ed] clear alignment between FDA, CorMedix, and its CMO on the strategy and activities needed to address the [First] CRL items, and the companies [we]re working collaboratively to complete this work." *Id*.

216. On January 6, 2022, *Truist* analysts issued some "Quick Thoughts"

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[102] CorMedix Inc., *CEO Matt David on Q3 2021 Earnings Call Transcript* (Nov. 09, 2021, 07:58 PM ET) ("3Q21 Call"), https://seekingalpha.com/article/4467632-cormedix-inc-crmd-ceo-matt-david-on-q3-2021-earnings-call-transcript.

[103] Jason N. Butler, PhD, Roy Buchanan, PhD, *3Q21 Update Manufacturing Activities Restarted for Defencath*, JMP SECURITIES LLC (Nov. 10, 2021).

following a conversation with CorMedix management earlier that day.[104] Specifically, the report highlighted the completion of the manual extraction study and the resolution of the identified deficiencies at the CMO's facilities. Based on that conversation, *Truist* analysts anticipated the DefenCath NDA would be resubmitted in the first half of 2022.

217. Then, on February 28, 2022, CorMedix announced that it had resubmitted the DefenCath NDA to address the manufacturing deficiencies identified by the FDA a year prior.[105] The 2/28/22 Press Release quoted Defendant Mounts as stating that "[t]he CorMedix team will continue to work collaboratively with FDA and [its] [CMO]" and that "we and the manufacturer have adequately addressed the concerns the [FDA] identified in the [First] CRL."

218. Industry analysts following CorMedix immediately issued glowing reports in response to this false assurance that problems relating to manufacturing were now a thing of the past. For example, *JMP* analysts highlighted that CorMedix "[m]anagement is confident that it and its third-party manufacturer have addressed

[104] Joon Lee, M.D., Ph.D., Les Sulewski, *CMC Back on Track and NDA Resubmission Possible 1H22*, TRUIST SECURITIES, INC. (Jan. 6, 2022).

[105] *Cormedix Inc. Announces Resubmission of New Drug Application for Defencath*, GLOBENEWSWIRE (Feb. 28, 2022) ("2/28/22 Press Release"), https://www.globenewswire.com/news-release/2022/02/28/2393197/0/en/Cormedix-Inc-Announces-Resubmission-of-New-Drug-Application-for-DefenCath.html.

all of the FDA's concerns" and relayed that CorMedix "indicate[d] that it plans to continue to work collaboratively with the FDA and its contract manufacturer regarding the NDA submission/review and the responses to the PAAL."[106] Because "the [C]ompany and its manufacturing partner gained clear alignment with the FDA on steps needed to address the CRL questions," the *JMP* analysts "remain[ed] confident in a high probability of approval." *Id.*

219. Similarly, *Truist* analysts noted that the day's news was "a huge relief" after "some drama and recent change of leadership."[107] They further noted that "previously, the [CorMedix] mgmnt stated that the NDA can be resubmitted without completion of full stability test," but "then, the Street learned that the FDA requested an 'in-process qualification study' / 'manual extraction study' which necessitated production of new batches and new stability tests." *Id.*

220. Then, on March 28, 2022, CorMedix announced that the DefenCath NDA resubmission had been accepted for filing as a Class 2 response, warranting a 6-month review cycle, including an advisory committee presentation or re-

[106] Jason N. Butler, PhD, Roy Buchanan, PhD, *DefenCath NDA Re-Submission a Positive Start to 2022*, JMP SECURITIES LLC (FEB. 28, 2022).

[107] Joon Lee, M.D., Ph.D., Les Sulewski, *DefenCath NDA Resubmitted. Not out of The Woods But Moving in Right Direction*, TRUIST SECURITIES, INC. (Feb. 28, 2022).

inspection.[108] Defendant Mounts is quoted in the 3/28/22 Press Release as stating "***CorMedix and our [CMO] have adequately addressed the concerns the [FDA] identified during the review of the original NDA and we are committed to working jointly to ensure a successful inspection.***"

221. Likewise, the next day, during the Company's conference call for the fourth quarter of 2021, Defendant Mounts stated that "CorMedix and the [CMO] have adequately addressed the concerns identified by FDA…" and that ***"[w]e are committed to providing updates to investors as appropriate over the coming months during the review process.***"[109] She also emphasized that "it is important to anticipate ***potential supply chain challenges and ensure multiple sources are in place to provide adequate inventory."*** *Id.*

222. At the time those statements were made (¶¶220-21, *supra*), Defendants CorMedix and Mounts knew or recklessly ignored that the Company's CMO was not meeting cGMP standards, and that the FDA had observed

[108] *CorMedix Inc. Announces FDA Acceptance of Resubmission of New Drug Application for Defencath*, GLOBENEWSWIRE (Mar. 28, 2022) ("3/28/22 Press Release"), https://www.globenewswire.com/news-release/2022/03/28/2411002/0/en/CorMedix-Inc-Announces-FDA-Acceptance-of-Resubmission-of-New-Drug-Application-for-DefenCath.html.

[109] *CorMedix Inc. (CRMD) CEO Matt David on Q4 2021 Results – Earnings Call Transcript*, SEEKING ALPHA (Mar. 29, 2022) ("4Q21 Call"), https://seekingalpha.com/article/4498557-cormedix-inc-crmd-ceo-matt-david-on-q4-2021-results-earnings-call-transcript.

manufacturing deficiencies at the third-party facility supplying one of the key active pharmaceutical ingredients (API) of DefenCath, heparin, for the U.S. market (*See* Section V.A.4). Indeed, unbeknownst to investors, those same deficiencies had resulted in the issuance of a Form 483 by the FDA on February 4, 2022, to the Company's API manufacturer, and warranted requests for corrective actions, yet, Defendants said nothing.

223. As a result of these misleading statements, analysts "remain[ed] confident that there is clear alignment between the FDA, CorMedix, and its [CMO] on the necessary information to address the CRL." Further, since "the FDA has scheduled an onsite inspection of the [CMO]," analysts were "confiden[t] that the manufacturing items in the CRL can be fully addressed ahead of the PDUFA date."[110]

224. The charade continued after Defendant Todisco took the helm. Indeed, *Truist* analysts "view[ed] his onboarding as a positive sign for CRMD and DefenCath" because they "expect[e]d Mr. Todisco to have done a fair amount of due diligence before deciding to join CRMD at such a critical juncture."[111]

225. In his first opening remarks as CEO, which was during the Company's

[110] Jason N. Butler, PhD, Roy Buchanan, PhD, *4Q/FY21: DefenCath NDA Review Underway for Likely Approval This Year*, JMP SECURITIES LLC (MAR. 30, 2022).

[111] Joon Lee, M.D., Ph.D., Les Sulewski, *Incoming CEO With Strong Commercial Background Bodes Well For DefenCath*, TRUIST SECURITIES, INC. (Mar. 29, 2022).

conference call for the first quarter of 2022, held on May 12, 2022, Defendant Todisco stated that "any FDA inspection of our CMO will assess the commercial readiness of the facility and manufacturing operations beyond those specific to DefenCath."[112] Defendant Todisco went on to add that "an ongoing work stream to identify U.S.-based CMOs that could be utilized for expanded manufacturing capacity to support commercial launch and for development of a pre-filled syringe format" but omitted that because CorMedix's CMO was still not meeting cGMP standards, the Company was at a substantial risk of receiving a second CRL and would likely need to find alternative manufacturing facilities if it was ever going make FDA approval a reality.

226. In addition, at no time during the 1Q22 Call did Defendant Todisco disclose the already materialized risk of failing to achieve FDA approval as a result of the major manufacturing deficiencies identified at the facility manufacturing CorMedix's key API, heparin. Indeed, Defendant Todisco failed to disclose material information when he specifically referenced the "continuing initiatives to dual source key components and active ingredients in order to de-risk … potential governmental regulatory actions at any key supplier" and purported to respond to a

[112] *CorMedix Inc. (CRMD) CEO Joe Tosdico on Q1 2022 Results – Earnings Call Transcript*, SEEKING ALPHA (May 12, 2022) ("1Q22 Call"), https://seekingalpha.com/article/4510981-cormedix-inc-crmd-ceo-joe-todisco-on-q1-2022-results-earnings-call-transcript.

specific question about "what kind of preparations [the Company was] making in terms of launch in terms of commercial prep and manufacturing supply ahead of time." Instead of disclosing the high risk to the DefenCath NDA resulting from the known manufacturing deficiencies at the Company's API supplier, Defendant Todisco simply stated that "in terms of activities that we are currently undertaking, we are doing right now all the typical prelaunch planning."

227. Likewise, Defendant Todisco omitted disclosure when he presented at the June 15, 2022 JMP Securities Life Sciences Conference – despite being told that investors "are focused on the manufacturing inspection process" and being specifically asked "[i]s everything there moving forward and still gives you confidence that [FDA inspection] can be completed in time to enable an approval later this quarter?"[113] In his response, Defendant Todisco double-downed on the Company's CMO and its ability to maintained cGMP standards, stating, "our contract manufacturer is a reputable – highly reputable European manufacturer. I think they're going to take all care to work diligently through any observation and work with the FDA on, if necessary, improving any compliance concerns FDA could raise." And when followed up with the question, "has the company addressed all the questions appropriately?" Defendant Todisco provided a resounding "Yes, yes."

[113] Edited Transcript, CRMD.OQ – CorMedix Inc at JMP Securities Life Sciences Conference REFINITIV STREETEVENTS (Jun. 15, 2022, 02:30PM) ("JMP Transcript").

228. The CorMedix Defendants' statements thus conveyed to investors that the Company had closely worked with its third-party manufacturers and suppliers to ensure that it could finally demonstrate that it could manufacture DefenCath for commercial use according to cGMP standards. As *Truist* analysts noted, "[w]ith CMC issues likely in the rear-view, CRMD is making several strategic moves that bolsters our confidence in commercial prospects of DefenCath."[114]

229. But after markets closed on August 8, 2022, CorMedix disclosed that its CMO still had manufacturing deficiencies *via* its announcement of yet another CRL "from the FDA stating that the DefenCath NDA cannot be approved until deficiencies recently conveyed to the [CMO] and the supplier of the [API] heparin during inspections are resolved to the satisfaction of FDA."[115] Despite receiving the First CRL as a result of identified deficiencies in the manufacturing of another drug at its contractor's facility, CorMedix failed to sufficiently prepare for "the FDA conduct[ing] a recent inspection unrelated to DefenCath at the facility of the company's heparin supplier, which culminated in the API supplier receiving a warning letter as a result of manufacturing deficiencies for a non-heparin API." As a result, "by way of the CRL, the FDA has now informed the company that

[114] Joon Lee, M.D., Ph.D., Les Sulewski, *Strong Mgmnt And SAB Bolsters Commercial Outlook For DefenCath Ahead of Late 3Q22 PDUFA*, TRUIST SECURITIES, INC. (May 12, 2022).

[115] 8/8/22 Press Release.

satisfactory resolution of these deficiencies will be required before the DefenCath NDA may be approved."

230. This news caused CorMedix's stock price to fall over 57%, causing Plaintiff and the putative class to suffer significant losses and damages.

4. Since the CorMedix Defendants concealed the identity of the Company's CMO and heparin manufacturer for commercialization in the U.S, throughout the Class Period, investors were in the dark about their lack of experience with FDA inspections and inability to maintain cGMP standards, and ensuing risk to the DefenCath NDA.

231. Defendants know, but still have not disclosed, the identity of CorMedix's CMO or heparin manufacturer, thus leaving investors in the dark about risks related to both manufacturers until they materialized and were disclosed by Defendants.[116] Nonetheless, Plaintiff's investigation has uncovered which CMO and heparin manufacturer most likely contracted with CorMedix. These Spanish manufacturers had very limited prior experience with FDA inspections and their manufacturing processes and protocols did not comply with certain cGMP standards during the Class Period, as seen in the FDA's on-site inspections.

[116] Plaintiff has filed a Freedom of Information Act (FOIA) request with the FDA seeking information related to CorMedix's manufacturing. If Plaintiff receives relevant information, Plaintiff reserves the right to amend this complaint.

i. CorMedix's CMO for the U.S. market – ROVI

232. In May 2020, CorMedix formed a wholly-owned subsidiary in Madrid, Spain while the country was beginning to ease its COVID-19 lockdown restrictions, but did not explain why to investors. On information and belief, the reason appears to be that the manufacturing facility of the Company's most likely CMO is in Madrid, Spain: ROVI Contract Manufacturing, S.L., owned by Laboratorios Farmacéuticos ROVI ("ROVI"). This information and belief is based on CorMedix's disclosures about its CMO purportedly being in Western Europe and having experience manufacturing drugs sold in the U.S. and with drug/device combinations like DefenCath.[117] ROVI's Madrid facility specializes in aseptic filling small volume parenterals in pre-filled syringes and vials, with an annual capacity of 180 million syringes and 50 million vials.[118] In addition, the information and belief is based on CorMedix's disclosures regarding the "proposed future installation of new equipment" at its CMO's facility on March 9, 2021 and the "delays" at its CMO relating to "issues … unrelated to DefenCath manufacturing activities" on September 7, 2021 corresponding most closely to what was happening at ROVI with regard to its manufacturing for Moderna during that time.

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[117] *See* 3/2/21 Truist Report (Cormedix "management shared with us that [its] CMO is based in Western Europe" and "manufactures drugs sold in the U.S.").

[118] *ROVI Contract Manufacturing*, OUTSOURCING-PHARMA.COM, https://www.outsourcing-pharma.com/Suppliers/ROVI-Contract-Manufacturing (last visited Dec. 3, 2021).

233. By July 9, 2020, Defendants knew or recklessly ignored that ROVI had agreed to do "large-scale, commercial fill-finish manufacturing of Moderna's" COVID-19 vaccine candidate at ROVI's Madrid facility.[119] As part of the deal, ROVI was to "provide vial filling and packaging capacity by procuring **a new production line and equipment for compounding, filling, automatic visual inspection and labeling** to support production of hundreds of millions of doses of the vaccine candidate … to supply markets outside of the U.S. starting in early 2021." *Id.* Based on FDA guidelines (*see supra* ¶¶72-84) and/or communications with the FDA, CorMedix knew or should have known that it needed to provide to the FDA, information about any new production line and/or equipment at the facility manufacturing DefenCath – even if it was unrelated to the manufacturing of DefenCath.

234. By April 29, 2021, Defendants knew or recklessly ignored that ROVI would be investing in new production lines at its Madrid facility "where it bottles, or 'fills and finishes' Moderna vaccines for markets" other than the US in order to "double its capacity to bottle" the vaccine.[120] Again, based on FDA guidelines (*see*

[119] ROVI, *Moderna and ROVI Announce Collaboration for Outside the United States Fill-Finish Manufacturing of Moderna's COVID-19 Vaccine Candidate* (Jul. 9, 2020), https://roviservices.com/wp-content/uploads/2020/12/ROVI_Press-release_Moderna_1.pdf.

[120] Reuters, *Spain's Rovi Will Double Its Capacity to Bottle Moderna's COVID-19*

supra ¶¶72-84) and/or communications with the FDA, CorMedix knew or recklessly ignored that it needed to provide the FDA information about any new production lines at the facility manufacturing DefenCath – even if they were unrelated to the manufacturing of DefenCath.

235. By July 27, 2021, Defendants knew or recklessly ignored contaminants in vials manufactured by ROVI, which required ROVI to conduct testing, as Moderna had publicly warned customers outside the U.S. of temporary delays in its COVID-19 vaccine shipments resulting from a testing operation by overseas manufacturing partners – one of whom was known to be ROVI.[121] Based on FDA guidelines (*see supra* ¶¶72-84) and/or communications with the FDA, CorMedix knew or should have known that it needed to provide the FDA with information about testing being done at the facility manufacturing DefenCath – even if it was unrelated to the manufacturing of DefenCath.

236. By August 26, 2021, Defendants knew or recklessly ignored that Japan had halted the use of over 1.6 million doses of Moderna's COVID-19 vaccine after "[u]nspecified contaminants were discovered in nearly 40 doses of the vaccine at

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Vaccines, U.S. NEWS (Apr. 29, 2021, 02:52 AM), https://www.usnews.com/news/world/articles/2021-04-29/spains-rovi-will-double-its-capacity-to-bottle-modernas-covid-19-vaccines.

[121] *Moderna warns of Covid-19 vaccine delivery delays for customers outside US*, RT.com (Jul. 27, 2021, 18:43), https://www.rt.com/news/530406-moderna-covid-vaccine-delivery-disruption/.

eight locations across Japan, prompting the decision to pull the lot that included them, as well as two other lots produced at the same location[.]"[122] Later that day, ROVI admitted that "the origin of this incident may be in one of its manufacturing lines and it was conducting an investigation following the standard procedure for such cases" as well as putting on hold "two adjacent lots … as a precaution."[123]

237. By September 1, 2021, Defendants knew or recklessly ignored the results of ROVI's investigation as they were made public.[124] ROVI's root cause analysis report identified "the most probable cause of the particulates" as "related to friction between two pieces of metal installed in the stoppering module of the production line due to an incorrect set-up. The two pieces are the star-wheel and the stoppers feeding device piece which feeds stoppers into the star-wheel." ROVI believed "that this condition occurred during the assembling of the line prior to

[122] Ben Dooley and Hisako Ueno, *Japan halts 1.6 million doses of the Moderna vaccine over contamination worries*, THE NEW YORK TIMES (Oct. 28, 2021) https://www.nytimes.com/2021/08/26/world/japan-moderna.html.

[123] Clara-Laeila Laudette, *Rovi investigating possible Moderna vaccine contamination, no safety issues so far*, REUTERS (Aug. 26, 2021, 12:27 PM EDT), https://www.reuters.com/world/europe/rovi-investigating-possible-moderna-vaccine-contamination-no-safety-issues-so-2021-08-26/.

[124] *Laboratorios Farmaceuticos Rovi S A : ROVI informs about the joint statement from Moderna and Takeda on the investigation of suspended lots of the vaccine*, MARKETSCREENER (Sept. 1, 2021, 03:52 PM EST), https://www.marketscreener.com/quote/stock/LABORATORIOS-FARMACEUTICO-388853/news/Laboratorios-Farmaceuticos-Rovi-S-A-ROVI-informs-about-the-joint-statement-from-Moderna-and-Takeda-36303039/.

production of [the impacted batch] and was a result of improper alignment during a line changeover before starting this batch." *Id*. Moderna independently analyzed and confirmed that the particulate were grade 316 stainless steel, which was consistent with the root cause investigation. *Id*. ROVI took the following steps to correct and prevent future defects:

- Full inspection of the manufacturing line;
- Improving standard operating procedure for changeover of manufacturing line; and
- Setting alert inspection limits in the automatic visual inspection, as an internal process control. *Id.*

238. By October 1, 2021, Defendants knew or recklessly ignored that ROVI had discovered contaminants in some vials in July 2021, and allowed supplies from that same production to pass inspection and ship to Japan.[125]

239. By October 21, 2021, Defendants knew or recklessly ignored that the FDA had delayed granting marketing authorization for Risperidone ISM, an injectable antipsychotic for the treatment of schizophrenia in the research phase, pending an on-site inspection of ROVI's manufacturing facility in Spain in light of outstanding concerns.[126] Previously on September 24, 2021, ROVI had received a

[125] Rocky Swift, *Japan's Takeda says 'human error' caused contamination of Moderna vaccines*, REUTERS (Oct. 1, 2021, 01:17 AM EDT), https://www.reuters.com/world/asia-pacific/japans-takeda-says-human-error-caused-contamination-moderna-vaccines-2021-10-01/.

[126] ROVI, *FDA delays its decision on Respiradone ISM®*, ROVI.ES (Oct. 21, 2021, 15:42), https://www.rovi.es/en/content/fda-delays-its-decision-risperidone-ismr.

CRL from the FDA citing outstanding questions relating to the documents submitted in support of its marketing authorization application. ROVI admitted to only addressing some, not all, of the FDA's noted concerns.

240. By April 8, 2022, Defendants knew or recklessly ignored that ROVI had announced a recall of a lot of the Moderna COVID-19 vaccine due to a foreign body being found in a vial, manufactured at ROVI's facility in Spain.[127] While no safety concerns had been reported in individuals who received the vaccine from this lot, out of an abundance of caution, the company initiated the recall.

241. By June 27, 2022, Defendants knew or recklessly ignored that the FDA had audited ROVI "and issued inspectional observations (*via* FDA Form 483)."[128] This inspection appears to have been the PAI that Defendants claimed to have prepared for after receiving the First CRL.

242. Because Defendants did not disclose the identity of CorMedix's CMO and/or other material facts about the CMO's lack of experience with FDA inspections and maintaining cGMP standards when adding new production lines and equipment or changing drug products in the manufacturing line, and instead touted the Company's successful interactions with the FDA and manufacturing of

[127] ROVI, Recall Notification of Lot #0000190A, ROVI.ES (Aug. 4, 2022), https://www.rovi.es/en/content/recall-notification-lot-000190a.

[128] *483 Laboratorios Farmaceuticos Rovi S.A., Jun 2022*, FDAzilla.com, https://fdazilla.com/store/form483/3010705046-20220627.

DefenCath, investors had no reason to expect the First CRL, delays in the resubmission due to manufacturing deficiencies related to the CMO's process for manufacturing DefenCath and protocols relating to changeover of manufacturing lines and visual inspections of drug products, nor did they expect receipt of the Second CRL.

ii. CorMedix's API manufacturer of heparin for the U.S. market – BioIberica

243. On information and belief, CorMedix's most likely heparin supplier is also in Spain, BioIberica, SAU ("BioIberica"), who produces 20% of the world's heparin API.[129] This information and belief is also based on CorMedix's disclosures about the "recent inspection unrelated to DefenCath at the facility of the company's heparin supplier, which culminated in the API supplier receiving a warning letter as a result of manufacturing deficiencies" on August 8, 2022[130] most closely corresponding to what was happening at BioIberica's Barcelona facility in 2022.

244. By February 4, 2022, Defendants knew or recklessly disregarded that the FDA had observed five areas of manufacturing deficiencies during its inspection of the drugs substance manufacturing facility of BioIberica in Barcelona, Spain

[129] *Emprendedores magazine recognizes the global leadership of BioIberica in the production of heparin*, BIOIBERICA.COM (Aug. 4, 2021), https://www.bioiberica.com/en/media/news/heparina/emprendedores-magazine-recognises-global-leadership-bioiberica-production-heparin.

[130] 8/8/2022 Press Release.

which related to microbiological contamination and improper cleaning procedures.[131] Such deficiencies included:

- Not validating "cleaning procedures for equipment used in the campaign manufacture of drug substances … to facilitate[] adequate cleaning and contamination prevention measures."
- Not establishing control procedures "which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of the drug substance."
- "The quality control unit lacks responsibility to approve all procedures or specifications impacting on identity, strength, quality, and purity of drug substances."
- "There is no written testing program designed to assess the stability characteristics of drug substances."
- "Written records of investigations into unexplained discrepancies do not always include conclusions and follow-up which are adequately justified."

245. By June 30, 2022, Defendants knew or recklessly disregarded that the FDA had issued BioIberica a "warning letter summariz[ing] significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API)."[132] That letter focused on BioIberica's failure to:

- "establish written procedures to monitor the progress and control the performance of processing steps that may cause variability in the quality

[131]U.S. Dept. of Health and Human Services, Food and Drug Administration, *Form FDA 483 Inspectional Observations* – BIOIBERICA, S.A.U., (Date Issued: Feb. 4, 2022), https://www.fda.gov/media/159142/download.

[132] U.S. Food & Drug Admin., *Warning Letter – BioIberica,* SAUMARCS-CMS *629115,* (June 30, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bioiberica-sau-629115-06302022.

characteristics of your intermediates and API" and

- "ensure that reworked batches have been subjected to appropriate evaluation and stability testing to show that the reworked material is of equivalent quality to that produced by the original process." *Id.*

246. As of June 30, 2022, BioIberica still had not "provide[d the FDA] interim measures until [its] proposed actions are complete," "evaluated the stability of reworked batches currently on the market," or established "an adequate ongoing program for monitoring process control to ensure stable manufacturing operations and consistent drug quality." *Id*. As a result, the FDA "strongly recommend[ed] engaging a consultant qualified to evaluate your operations to assist your firm in meeting CGMP requirements." *Id*.

247. Yet at no time during the Class Period did the CorMedix Defendants disclose any of the manufacturing issues at the facility of its CMO or its heparin manufacturer, much less warn investors that manufacturing issues existing at the facility of the CMO and of the heparin manufacturer would prevent CorMedix from obtaining FDA approval.

248. Indeed, the Officer Defendants admit their knowledge of the deficiencies at Bioiberica's facility in the Company's 8/8/22 Press Release, which notes that "CorMedix [had] sought guidance from FDA as to whether these deficiencies would impact the timing of approval of the DefenCath NDA." While the Officer Defendants appear to recognize that the deficiencies were serious enough to warrant inquiring with the FDA, they chose not to disclose these known

deficiencies until they announced the Second CRL.

B. Materially False and Misleading Statements and Omissions During the Class Period[133]

249. The Class Period begins on October 16, 2019, when pre-market, the Company issued a press release entitled "CorMedix Completes Successful CMC Interaction with the FDA." That same day, the Company filed the 10/16/19 Press Release with the SEC as Exhibit 99.1 to the Current Report on Form 8-K, signed by Defendant Cook pursuant to the requirements of the Exchange Act. The 10/16/19 Press Release stated, in relevant part, that:

> ***The FDA was supportive of Neutrolin's proposed manufacturing program***, including the active pharmaceutical ingredients (API), the container closure and testing, and ***indicated that it will conduct a thorough review of all of the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of NDA filing. No further CMC meetings with FDA are planned prior to NDA submission.***

250. Defendant Baluch was further quoted in the 10/16/19 Press Release as stating that "[w]e anticipate that ***Neutrolin can be approved in the second half of 2020*** and we intend to launch Neutrolin commercially in the US promptly after its approval either by ourselves or with a partner."

251. The statements referenced in ¶¶249-50 were materially false and

[133] In this Section, the alleged false and/or misleading portions of the statements are both bolded and italicized.

misleading and/or omitted material facts, including that: (i) the FDA raised concerns regarding the CMC information presented, including but not limited to, quality control data, and requested additional data be submitted with the NDA; (ii) deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (iii) the CorMedix Defendants had failed to ensure the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (iv) therefore, the additional data CorMedix and its CMO were preparing to submit was insufficient to demonstrate the CMO's commercial readiness; and (v) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

252. On November 14, 2019, the Company issued its 3Q19 Press Release that announced, in relevant part:

> ***The FDA was supportive of Neutrolin's proposed manufacturing program***, including the manufacture of the active pharmaceutical ingredients (APIs), the container closure and testing, and ***indicated that it will conduct a thorough review of all of the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of the NDA filing. No further CMC meetings with the FDA are planned prior to the NDA submission***.

253. The statements referenced in ¶252 were materially false and misleading and/or omitted material facts, including that: (i) the CorMedix

Defendants had downplayed the true scope of the FDA's request for more data; (ii) the FDA raised concerns regarding the CMC information presented, including but not limited to quality control data, and requested additional data be submitted with the NDA; (iii) deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (iv) the CorMedix Defendants had failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (v) therefore, the additional data CorMedix and it's CMO were preparing to submit was insufficient to demonstrate the CMO's commercial readiness; and (vi) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

254. Later that day, the Company hosted its 3Q19 Call with investors and analysts at 4:30 ET to discuss, among other things, its 3Q19 financial results. During the call, Defendant Mounts explained:

> Manufacturing of the drug product must be shown to be reproducible and reliable through validation study. Stability [a]s a product needs to be demonstrated with extensive data and subject[ed] to conditions likely to be encountered in commercial distribution to ensure the quality as a product. ***As manufacturing experience expand[s], data on drug substance and drug product are generated and we s[ought] feedback from the FDA in quarter four to discuss the data that have been developed to support the NDA.*** We believe that it is important to obtain guidance from FDA to ensure that we have all of the CMC information that the agency is expecting and can proactively address any question

FDA may have.

As we announced the press release on October 16, ***FDA provided guidance on the CorMedix CMC program and indicated data that will need to be available in the NDA for [its review]***.

255. In addition, during the 3Q19 Call, Defendant Armstrong stated, in relevant part:

The interaction with the FDA [was] on the CMC known as the chemistry manufacturing controls. As Phoebe as indicated***, is important and critical for the NDA and depending on what is requested [CorMedix] needs to assure [it] completes the work in time to not [delay] the NDA filing.*** As our press release of 16 October indicated the outcome of our [inter]action with the FDA was very positive. FDA was supportive of the core manufacturing processes for the drug product and the active pharmaceutical ingredients for the inclusion as part of the NDA submission.

FDA did request some additional data which we are working to complete, so we're optimistic that the CMC module we completed a[s] plan[ned] for filing with the FDA. FDA did indicate that it will conduct a thorough review of all of the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of the NDA review. No further CMC meetings with FD[A] are planned prior to the NDA submission.

256. Defendant Armstrong went on to add, in relevant part, that:

…As mentioned previously, ***I have working with me a very experienced and competent team, they have the needed breadth and depth in the requirements for sourcing, manufacturing, distribution and quality assurance that is necessary for both the US and foreign markets.***

* * *

[T]he drug product manufacturer, that's [the vial] is in place and ***processes have been established and appropriate validation testing completed to enable manufacture of launch quantities.***

257. The statements referenced in ¶¶254-56 were materially false and

misleading and/or omitted material facts, including that: (i) the CorMedix Defendants had downplayed the true scope of the FDA's request for more data; (ii) the FDA's request for additional data reflected the existence of deficiencies at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (iii) likewise, the FDA raised concerns regarding the CMC information presented, including but not limited to, data sufficient to show that the labeled volume of the drug product could be consistently withdrawn from vials, despite existing in-process controls; (iv) CorMedix's "team", including the Officer Defendants, failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (v) therefore, the additional data CorMedix and its CMO were preparing to submit was insufficient to demonstrate the CMO's commercial readiness; and (v) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

258. The Company issued its 2/3/20 Press Release, which stated, in relevant part, that "***CorMedix remains on schedule for a potential NDA approval during the second half of 2020***."

259. The statement referenced in ¶258 was materially false and misleading and/or omitted material facts, including that: (i) deficiencies existed at the facility

manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) likewise, the FDA had already raised concerns regarding the CMC information presented, including but not limited to, data sufficient to show that the labeled volume of the drug product could be consistently withdrawn from vials, despite existing in-process controls; (iii) the Officer Defendants had failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (iv) therefore, the additional data CorMedix and its CMO were preparing to submit would be insufficient to demonstrate the CMO's commercial readiness; and (v) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

260. On March 16, 2020, CorMedix filed its 2019 10-K with the SEC, signed by Defendants Baluch, Kaplan, Dillione, Dunton, Khan, and Lekfowitz. The 2019 10-K included certain "Risks Related to Dependence on Third Parties", which unbeknownst to investors, had already materialized.

261. First, the 2019 10-K warned that "***[d]ata provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading, or incomplete***." Specifically, it stated that "[w]e rely on third-party vendors, scientists, and collaborators to provide us with significant data

and other information related to our projects, clinical trials, and business. ***If such third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially adversely affected.***"

262. Second, the 2019 10-K warned that:

> Our contract manufacturers ***may not be able to comply with the applicable FDA regulatory requirements, which could result in delays to our product development programs, could result in adverse regulatory actions against them or us, and could prevent us from ultimately receiving product marketing approval.*** They also generally must pass an FDA preapproval inspection for conformity with cGMPs before we can obtain approval to manufacture our product candidates and will be subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. ***If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP***, ***we may experience manufacturing errors resulting in*** defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery***, delay or prevention of filing or approval of marketing applications for our products,*** cost overruns or other problems that could seriously harm our business. ***Not complying with FDA requirements could*** result in a product recall or ***prevent commercialization of our product candidates and delay our business development activities***. In addition, ***such failure could be the basis for the FDA to issue a warning or untitled letter or take other regulatory or legal enforcement action, including*** recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, ***refusal to approve pending applications or supplemental applications***, and potentially civil and/or criminal penalties depending on the matter.

263. Appended as exhibits to the 2019 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein Defendant Baluch certified that "[t]he [2019 10-K] fully complies with the requirements of Section

13(a) or 15(d) of the [Exchange Act], as amended[,]" and that "***[t]he information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company***."

264. Later that day, CorMedix hosted its 4Q19 Call with investors and analysts at 4:30 ET to discuss, among other things, its 4Q19 financial results. During that call, Defendant Baluch stated, in relevant part:

> I'd like to re-emphasize, number one, we are pleased to report to our shareholders that ***the effort to move the regulatory process forward with the FDA is on track***.
>
> * * *
>
> ***The significant experience Phoebe [Mounts] brings in regulatory, Jack [Armstrong] in manufacturing and supply chain***, Paul in medical affairs and Liz in clinical operation, ***coupled with my Cialis and Byetta launch experience in the US just to name a few recent launches makes for a winning team***.

265. The statements referenced in ¶¶261-64 were materially false and misleading and/or omitted material facts, including that: (i) deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) CorMedix's "winning team", including the Officer Defendants, failed to ensure the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (iii) therefore, the additional data CorMedix and its CMO were preparing to submit was insufficient to demonstrate the CMO's commercial readiness; and (iv) as a result,

the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

266. CorMedix issued its 4/22/20 Press Release, announcing it had completed the sale of $5.5 million of NOL tax benefits through the New Jersey Technology Business Tax Certificate Transfer Program. In that press release, Defendant Baluch was quoted as stating, in relevant part "***[w]e have remained on schedule towards an anticipated approval in the second half of 2020***, subject of course to possible delays at FDA due to the coronavirus pandemic."

267. The statement referenced in ¶266 was materially false and misleading and/or omitted material facts, including that: (i) deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) likewise, the FDA had already raised concerns regarding the CMC information presented, including but not limited to, data sufficient to show that the labeled volume of the drug product could be consistently withdrawn from vials, despite existing in-process controls; (iii) the CorMedix Defendants had failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (iv) therefore, the additional data CorMedix and its CMO were preparing to submit was insufficient to demonstrate the CMO's commercial readiness; and (v) as a result, the DefenCath

NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

268. The 5/11/20 Press Release quoted Defendant Baluch as stating, in relevant part, that "[w]e have been working remotely since mid-March, a transition we have made with little disruption and as a result ***we are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020***."

269. Later that day, CorMedix hosted a conference call with investors and analysts at 4:30 ET to discuss, among other things, its 1Q20 financial results ("1Q20 Call"). During that call, in response to a question from analyst Daniel Ferry of LifeSci Advisors about whether the Company "can potentially get approval in the second half of 2020[,]" Defendant Mounts stated, in relevant part, that:

> At this time, ***we are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020***. ***We are all very cognizant of preparing an NDA that is complete and provides all of the information in the agency's required format to ensure an efficient review.*** We focused on discussions with FDA in 2019 to make sure that we understood the FDA's expectations to evaluate the manufacturing as well as safety and effectiveness of DEFENCATH. We also believe that by being attentive to the quality and completeness of the submission that we are assisting the FDA to achieve an efficient review process to enable approval in the second half of 2020.

270. In addition, Defendant Baluch stated, in relevant part, later during the 1Q20 Call that "we are extremely pleased that ***the effort to move the regulatory process forward with the FDA is on track. We are maintaining our guidance for***

an anticipated decision on approval of the NDA in the second half of 2020."

271. The statements referenced in ¶¶268-70 were materially false and misleading and/or omitted material facts, including that: (i) deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) likewise, the FDA had already raised concerns regarding the CMC information presented, including but not limited to, data sufficient to show that the labeled volume of the drug product could be consistently withdrawn from vials, despite existing in-process controls; (iii) the CorMedix Defendants had failed to ensure the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (iv) therefore, the additional data that CorMedix and its CMO were preparing to submit was insufficient to demonstrate the CMO's commercial readiness; and (v) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

272. During pre-market hours, CorMedix issued its 7/8/20 Press Release which stated, in relevant part, that "***all of the modules for the Defencath™ [NDA] have been submitted*** to the [FDA]" and that "***there has been ongoing dialogue with FDA as it reviews the submitted modules***."

273. The 7/8/20 Press Release also quoted Defendant Baluch, who

represented, in relevant part, that CorMedix was "very pleased to have ***completed the submission of the NDA, despite the limitations imposed by the COVID-19 pandemic, which delayed some required laboratory testing and our submission***."

274. The statements referenced in ¶¶272-73 were materially false and misleading and/or omitted material facts, including that: (i) the FDA's request for additional data reflected the existence of deficiencies at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) the required laboratory testing was likely the result of the FDA's request for additional information, therefore, the delayed submission is more likely a result of the foregoing deficiencies than limitations imposed by the COVID-19 pandemic; (iii) despite ongoing dialogue with the FDA, Defendants had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iv) the module containing CMC information, submitted as part of the DefenCath NDA, reflected those deficiencies; and (v) as a result, the DefenCath NDA submission could not obtain FDA approval in the second half of 2020.

275. CorMedix issued the 8/10/20 Press Release" that represented, *inter alia*, that CorMedix had "***[c]ompleted the rolling submission and review of the [NDA] for Defencath to the FDA*** for the prevention of … CRBSIs[] in patients undergoing hemodialysis via catheter."

276. Additionally, the 8/10/20 Press Release quoted Defendant Baluch, who stated, in relevant part, that "[w]e were pleased to announce ***the completion of our rolling submission for Defencath last month*** and look forward to providing updates on the acceptance for filing from FDA…We also are ***making necessary preparations for the launch of DefenCath in the U.S. hemodialysis market, following FDA approval***. We believe ***we have the team***, the focus, and a therapy that will meaningfully improve patient outcomes and are excited about the opportunities in front of us."

277. That same day, CorMedix filed its 2Q20 10-Q which stated, in relevant part, that "[i]n March 2020, the Company began the modular submission process for the NDA for Defencath for the prevention of CRBSI in hemodialysis patients, and recently announced ***on July 8, 2020, that submission of all modules for the NDA was completed.***"

278. Appended as exhibits to the 2Q20 10-Q were substantively the same SOX certifications referenced in ¶263, *supra*, signed by Defendants Baluch and David.

279. Later that day, CorMedix hosted its 2Q20 Call with investors and analysts at 4:30 ET to discuss, among other things, the 2Q20 financial results. During that call, Defendant Baluch stated, in relevant part, that:

> I'm very pleased by ***the submission to the FDA of the New Drug Application, or NDA, for DEFENCATH was completed in June***. This

> submission was completed using the rolling submission format granted by the FDA, which we started in March.
>
> ***Completing this filing was a major undertaking as the team had to work through the Chemistry Manufacturing and Control information, CMC,*** and a large volume of data generated due to the size of LOCK-IT-100 trial and the underlying health issues of the hemodialysis patient group…
>
> ***I'm proud of the team at CorMedix for bringing their collective experience to bear and completing a high quality submission…***
>
> …I'd also like to provide an update on ***several work efforts that are moving forward with the goal of being prepared when we receive NDA approval,*** so that DEFENCATH can be launched into the U.S. hemodialysis market as soon as possible.

280. In addition, during the 2Q20 Call, Defendant Mounts stated, in relevant part, that "***[t]he rolling submission was started in March and completed in June***. Consistent with the rolling submission and review process, ***FDA began an ongoing dialogue with us on the submission as it was in progress***." Defendant Mounts went on to add, "we are very grateful for the effort of the ***CorMedix team in preparing a high quality submission***."

281. During the 2Q20 Call, Wainwright analyst Ram Selvaraju asked, in relevant part, "if the DEFENCATH NDA is accorded priority review, does that by definition accord a six month review time frame to the NDA? Or could it potentially be approved in a faster time frame than that?"

282. To which, Defendant Mounts responded:

> [T]he PDUFA date, which will reflect a six month review goal, if we get a priority review, is the goal. And as you know, the review may occur and the approval may occur faster than that or it can take longer

> than that. It really depends on how long it takes FDA to work through the information in the NDA. And that's why ***we put a premium on making sure that we understood FDA's expectations in what they want to see in the NDA, doing those analysis and making sure that the NDA had the information that we wanted to get in there.***

283. The statements referenced in ¶¶275-80, 282 were materially false and misleading and/or omitted material facts, including that: (i) that the Company had not actually "ma[de] sure that [it] understood FDA's expectations in what they want to see in the NDA," had not "do[ne] those analysis" and had not "ma[de] sure that the NDA had the information" requested; (ii) the FDA's request for additional data reflected the existence of deficiencies at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (iii) despite ongoing dialogue with the FDA, CorMedix "team", including the Officer Defendants, had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iv) the module containing CMC information, submitted as part of the DefenCath NDA, reflected those deficiencies; and (v) as a result, the DefenCath could not obtain FDA approval.

284. CorMedix issued its 8/31/20 Press Release announcing the FDA's acceptance for filing and priority review of the DefenCath NDA, setting a PDUFA date of February 28, 2021, for the completion of its review. That press release stated, in relevant part, "[t]he FDA had previously granted a ***rolling submission and review,***

which the Company completed at the end of June."

285. The 8/31/20 Press Release also quoted Defendant Mounts, who asserted, in relevant part, that "we look forward to ***continuing to work together [with the FDA] expeditiously to complete the review of the Defencath NDA*** to address an unmet medical need."

286. The statements referenced in ¶¶284-85 were materially false and misleading and/or omitted material facts, including that: (i) the CorMedix Defendant's downplayed the true scope of their interactions with the FDA as the agency had already raised concerns regarding existing manufacturing records submitted as part of the NDA, and as part of its records inspection, had requested additional documents from the CMO to support its commercial readiness; (ii) deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsisten fill volume; (iii) despite ongoing dialogue with the FDA, CorMedix's "team", including the Officer Defendants, had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iv) the module containing CMC information, submitted as part of the DefenCath NDA, reflected those deficiencies; and (v) as a result, the DefenCath NDA could not obtain FDA approval.

287. CorMedix issued its 11/5/20 Press Release, reporting its 3Q20 results

and providing a business update. That press release represented, in relevant part, that "***CorMedix continues its interactions with the FDA regarding the ... NDA[] for Defencath™*** for the prevention of ... CRBSIs[] in patients undergoing hemodialysis via central venous catheter."

288. The press release also quoted Defendant Baluch, who stated, in relevant part, that "[w]e believe ***we have the team***, the focus, the resources, and a novel catheter lock solution that will meaningfully improve patient outcomes and are excited about the opportunities in front of us."

289. That same day, CorMedix filed its 3Q20 10-Q stating, in relevant part:

> In March 2020, we began the modular submission process for the NDA for Defencath for the prevention of CRBSI in hemodialysis patients, and recently ***announced on July 8, 2020, that submission of all modules for the NDA was completed***. In August 2020, the FDA accepted for filing the Defencath NDA… ***The FDA noted that … it had not identified any potential review issues at this time…***

290. Appended as exhibits to the 3Q20 10-Q were substantively the same SOX certifications referenced in ¶263, *supra*, signed by Defendants Baluch and David.

291. Later that day, CorMedix hosted a conference call with investors and analysts at 4:30 ET to discuss, among other things, the 3Q20 financial results ("3Q20

Call").[134] During that call, Defendant Baluch reiterated, in relevant part:

> As we disclosed on August 31, 2020, ***the submission to the FDA of the [] NDA[] for DEFENCATH which was completed in June*** has been accepted for filing…The FDA also noted that" it ***had not identified any potential review issues*** at that time.
>
> * * *
>
> …the CorMedix team has continued to prepare for DEFENCATH's anticipated commercial launch and continue to have discussions with many key players in the dialysis space, including the dialysis organizations and CMS. The interactions have been positive and ***clearly positions CorMedix to ensure that once DEFENCATH is approved by the FDA, it will be in the best possible position to successfully launch in the U.S. market***….

292. Defendant Mounts added to the 3Q20 Call, stating, in relevant part, "***FDA's review of the DEFENCATH new drug application is continuing expeditiously due to*** the engagement of FDA's review team and ***the tremendous effort of the CorMedix team***."

293. The statements referenced in ¶¶287-92 were materially false and misleading and/or omitted material facts, including that: (i) the CorMedix Defendant's downplayed the true scope of their interactions with the FDA such that the agency had already raised concerns regarding existing manufacturing records submitted as part of the NDA, and as part of its records inspection, had requested additional documents from the CMO to support its commercial readiness; (ii)

[134] *CorMedix Inc. (CRMD) CEO Khoso Baluch on Q3 2020 Results – Earnings Call Transcript*, SEEKING ALPHA (Nov. 8, 2020) ("3Q20 Call"), https://seekingalpha.com/article/4386793-cormedix-inc-crmd-ceo-khoso-baluch-on-q3-2020-results-earnings-call-transcript.

deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (iii) despite ongoing dialogue with the FDA, the CorMedix "team", including the Officer Defendants, had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iv) the DefenCath NDA reflected those deficiencies; and (v) as a result, the DefenCath NDA could not obtain FDA approval. Regardless of whether the FDA had used the exact phrase "review issue," it had already made clear to the CorMedix Defendants that manufacturing concerns would be critical to the DefenCath NDA.

294. On November 18, 2020, CorMedix issued its 11/18/20 Press Release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, announcing the FDA's decision that an advisory committee meeting for the DefenCath NDA was not needed.[135] That press release advised that "CorMedix has been notified that ***based on the [FDA]'s ongoing dialogue with the Company, discussion at an advisory committee is not needed, and it will continue to work on the application with CorMedix during the remainder of the review cycle***."

295. The 11/18/20 Press Release also quoted Defendant Baluch, who asserted that CorMedix and the FDA were working closely together on the DefenCath NDA, stating that "[w]e are very happy with ***the level of engagement***

[135] 11/18/20 Press Release.

between FDA and the CorMedix team during the NDA review process."

296. Additionally, the 11/18/20 Press Release quoted Defendant Mounts, who likewise asserted that CorMedix and the FDA were working closely together on the DefenCath NDA, stating that "the ***tremendous effort of the CorMedix team has resulted in continuing progress with the FDA in the review of the NDA*** and that the decision was made that ***no discussion with an advisory committee is needed***[,]" and that "[w]e intend to ***continue our effort and dialogue with the [FDA] to ensure that the priority review process can be completed expeditiously*** to address the unmet medical need…"

297. The statements referenced in ¶¶294-96 were materially false and misleading and/or omitted material facts, including that: (i) the CorMedix Defendant's downplayed the true scope of their interactions with the FDA such that the agency had already raised concerns regarding existing manufacturing records submitted as part of the NDA, and as part of its records inspection, had requested additional documents from the CMO to support its commercial readiness; (ii) deficiencies existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (iii) despite ongoing dialogue with the FDA, CorMedix "team", including the Officer Defendants, had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards;

(iv) the DefenCath NDA, reflected those deficiencies; and (v) as a result, the DefenCath NDA could not obtain FDA approval.

C. The Truth Slowly Leaks Out[136]

1. Partial Disclosure on March 1, 2021

298. On March 1, 2021, pre-market, the Company issued a press release, later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, titled "CorMedix Receives Complete Response Letter from FDA for DefenCath™ Catheter Lock Solution[,]" "announc[ing] that the [FDA] cannot approve the [NDA] for DefenCath … in its present form." Specifically, CorMedix informed investors:

> **FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility.** FDA did not specify the issues and **CorMedix intends to work with the manufacturing facility to develop a plan for resolution** when FDA informs the facility of the specific concerns. When we are informed of the issues, we will schedule an investor conference call to provide an update on our expected timeline for resolution. **Additionally, FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications.** CorMedix expects to be able to complete this requirement expeditiously.
>
> **Satisfactory resolution of these issues is required for approval of the DefenCath NDA by a pre-approval inspection and/or adequate manufacturing facility responses addressing these concerns.** If an inspection is required, the FDA is currently facing a backlog due to the pandemic and are actively working to define an

[136] In this Section, the alleged false and/or misleading portions of the statements are both bolded and italicized. The alleged corrective disclosure portion of the statements are only bolded.

> approach for scheduling outstanding inspections once safe travel may resume. CorMedix will request a meeting with the FDA, which we estimate will occur by mid-April, to obtain agreement with the Agency on our proposed plan for resolution of the issues at our third-party manufacturing facility.

299. On this news, CorMedix's stock price fell $8.16 per share, or 54.4%, to close at $6.84 per share on March 3, 2021. As *Truist* analyst Lee explained, the First CRL "***c[a]me[] as a surprise as the product has already been in production and commercial in the EU, albeit at limited capacity.***" (Emphasis in original).[137]

300. Despite this decline in the Company's stock price, CorMedix securities continued to trade at artificially inflated prices throughout the remainder of the Class Period, as a result of Defendants' continued misrepresentations and omissions regarding the true scope of the deficiencies plaguing the manufacturers of DefenCath, relating to the facilities themselves and the manufacturing process. As a result, investors were misled into believing that the issues causing the First CRL were minor and would be resolved quickly, enabling the Company to resubmit the DefenCath NDA in the 2021 calendar year. Moreover, based on the CorMedix Defendants' consistent assurances that they were working closing with their manufacturers and the FDA, investors were misled into believing that the Company had the control of manufacturing and quality of its drug product that was necessary

[137] Joon Lee, M.D., Ph.D., Les Sulewski, *CRL Due To CMC Issues. No Deficiencies Related to Efficacy Or Safety of Defencath*, TRUIST SECURITIES (Mar. 1, 2021).

to meet regulatory standards.

301. Indeed, after speaking to "the mgmnt team on the [First] CRL" on March 1, 2021, *Truist* analyst Lee of noted that the "40% selloff appears overdone" based on the "lack of fundamental issues with DefenCath itself."[138]

302. On March 9, 2021, CorMedix hosted its CRL Call, during which, Defendant Mounts stated, in relevant part:

> As I said, there were 6 facility deficiencies remaining at the conclusion of the assessment of the records request. ***Based on our discussions with the CMO, we believe these deficiencies can be resolved in the coming weeks***. For example, one deficiency results from the proposed future installation of new equipment, but it was apparently not clear to FDA that the equipment is unrelated to the manufacturer of DEFENCATH because FDA has requested details to assess the impact to production readiness for DEFENCATH.
>
> Three of the deficiencies involve activities associated with the vial filling line, in particular, the target filling volume. Additionally, a related approvability issue with the FDA's request communicated directly to CorMedix for a required ***manual extraction study to demonstrate that the labeled volume of the drug product can be consistently withdrawn from vials.*** As we noted in the March 1 press release, there is an existing in-process control to demonstrate fill volume within specifications. ***We have submitted data to FDA to demonstrate performance with the specifications but we intend to conduct the requested manual extraction study and expect it to be completed in the next several weeks***. Another deficiency identifies concerns an airflow visualization study, and ***will likely necessitate repeating the study to demonstrate adequate dynamic conditions*** in the study, ***which we believe can be accomplished in the next several weeks.***

[138] Joon Lee, M.D., Ph.D., Les Sulewski, *Selloff On CMC Issues Overdone. R BUY But PT To $30 (-$5) On Launch Delays*, TRUIST SECURITIES (Mar. 1, 2021).

> The sixth deficiency requests documentation to support appropriate closing of deviations or nonconformances. ***We are working with the CMO to provide existing documentation to demonstrate that corrective actions are adequate to assure production controls are in place and to ensure standard operating procedures are consistent with actual practices and documentation is completed in a timely manner***.

303. In addition, during the CRL Call, Defendant Armstrong stated, in relevant part:

> Consistent with industry practice, we continued to work closely with the CMO via site visits and regular conference calls to prepare for an FDA inspection after submission of the NDA. We manufactured and validated 3 commercial scale drug product batches. ***All drug product made at the CMO for validation batches and subsequent batches met specifications. The drug product*** was put on accelerated and normal stability testing and ***continues to meet specifications.***

304. Defendant Baluch further added during the CRL Call, in relevant part, that "[w]e are working as fast as we can, in concert with the CMO, which is fully cooperating to develop and execute the plan. We believe ***we have within CorMedix and the CMO, the resources and capabilities to achieve successful resolution of the manufacturing deficiencies to the satisfaction of the FDA***."

305. Later during the CRL Call, *JMP* analyst Jason Nicholas Butler asked for "more color you can give on FDA's issues with the vial finishing lines? Anything you can tell us about whether these lines are used solely for DEFENCATH or other products? Or anything that's unique or different about these lines versus other fill/finish facilities? And then, just in terms of your overfill margins, is there

anything you're doing different here? Or anything different to industry standard in terms of your overfill margins?"

306. Defendant Armstrong responded, in relevant part, "***[w]e are following the guidelines that are given, and we are following the guidelines on the overfill. And it's not different than we were doing before. We are within the guidelines***."

307. The statements referenced in ¶¶302-04, 306 were materially false and misleading and/or omitted material facts, including that: (i) despite claims of "working with the CMO", the CorMedix Defendants had failed to ensure processes were in place to assure the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (ii) the CMO's existing documentation was insufficient to show its methods of manufacturing and quality controls met cGMP standards; (iii) as a result, it would be necessary for the CMO to collect additional data, including but not limited to, an airflow visualization study, in order to achieve resolution of the identified deficiencies; (iv) the CMO's process for filling the vials was so flawed that the related deficiencies could not be resolved through the production of additional data alone, including the manual extraction study; (v) because the CMO's process for filling the vials was so flawed, it could only remedy deficiencies by changing its fill process to meet specifications; (vi) as a result, the CMO would need to conduct additional process qualification with subsequent

validation data to support; and (vii) as a result of insufficient documentation and inadequate processes relating to filling the vial, the CMO's ability to obtain the necessary data to assure the FDA that the identified deficiencies had been resolved would be delayed.

308. Then, on March 30, 2021, CorMedix issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, reporting its 4Q20 results and providing a business update.[139] That press release continued to generally advise that the "FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility, and has requested a ***manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from vials***" and "***CorMedix continues to work closely with our third-party manufacturing facility*** and is planning for a meeting with the FDA in mid-April to obtain agreement on the adequacy of our proposed plans for resolution of the deficiencies."

309. That same day, CorMedix filed an annual report on Form 10-K with the SEC, reporting its financial and operating results for the quarter and year ended

[139] *CorMedix Inc. Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update*, GLOBENEWSWIRE (March 30, 2021, 16:05 ET) ("3/30/21 Press Release"), https://www.globenewswire.com/news-release/2021/03/30/2201949/0/en/CorMedix-Inc-Reports-Fourth-Quarter-and-Full-Year-2020-Financial-Results-and-Provides-Business-Update.html.

December 31, 2020.[140] The 2020 10-K advised, *inter alia*:

> As we announced in March 2021, the FDA has informed us that it will not approve the NDA for DefenCath in its present form. The FDA noted concerns at the third-party manufacturing facility after a review of records requested by the FDA and provided by the manufacturing facility. ***We are working with the manufacturing facility to develop plans for resolution of the deficiencies***. Additionally, the FDA is requiring ***a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications.*** We expect to be able to complete this requirement expeditiously. Satisfactory resolution of these issues is required for approval of the DefenCath NDA by a pre-approval inspection and/or adequate manufacturing facility responses addressing these concerns.

310. Appended as exhibits to the 2020 10-K were substantively the same SOX certifications referenced in ¶263, *supra*, signed by Defendants Baluch and David.

311. Later that same day, Defendants hosted the Company's 4Q20 Call at 4:30ET to discuss, among other things, its 4Q20 financial results. During that call, Defendant Baluch assured investors that "we remain confident that ***we have the right team and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified.***"

312. In addition, during the 4Q20 call, Defendant Mounts advised:

> I will start with the all-important timeline. The timeline we outlined on March 1 and reiterated on March 9 for a planned meeting with the FDA in mid-April remains on track based on the progress we

[140] CorMedix, Inc., Annual Report (Form 10-K) (Mar. 30, 2021) ("2020 10-K").

have made. ***We have been working intensely with our third-party manufacturing facility to develop the proposed resolutions to the deficiencies.***

There has been a strong collaborative effort to develop responses for each of the six deficiencies identified by FDA for the manufacturing facility. In addition, we have developed the protocol for ***the manual extraction study being required by FDA to demonstrate that the labeled volume of the drug product can be consistently withdrawn from vials.***

I am pleased to announce that FDA has granted our request to meet with them to begin resolving the outstanding deficiencies. As we have previously stated, the purpose of the meeting with FDA is to obtain agreement with the agency on the adequacy of our proposed plans for resolution of the deficiencies. Our contract manufacturing organization will join us in the meeting with FDA.

As we planned, the meeting will occur in mid-April, and we will provide an update on our progress and timeline for resolution of the deficiencies after the meeting with FDA. Our goal is to ensure that FDA can conclude that the manufacturing facility is ready to support commercial operation for DEFENCATH without the need for an on-site inspection.

313. On the same call, regarding CorMedix's anticipated meeting with the FDA to discuss the DefenCath NDA, *JMP* analyst Jason Butler asked whether "you will actually have any of the work requested by FDA completed by the meeting, either in terms of documentation protocols, or the vial fill volume study or airflow visualization studies that they asked for," and whether "you've actually completed any, or have any new data to take to the meeting?" In response, Defendant Mounts assured investors, "yes, we obviously were involved in developing the proposed responses"; that "[s]ome of those proposed responses involve existing documentation"; that "***we ma[d]e sure that – -- where we could, we provided***

information that was responsive to the deficiency"; and that "***there is new information there for them to review for some of the responses***."

314. The statements referenced in ¶¶308-13 were materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) despite claims of "work[ing] closely" and "intensely" with the CMO, CorMedix's "team", including the Officer Defendants, had failed to ensure processes were in place to assure the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (ii) the CMO's existing documentation was insufficient to show its methods of manufacturing and quality controls met cGMP standards; (iii) as a result, it would be necessary for the CMO to collect additional data, including but not limited to, an airflow visualization study, in order to achieve resolution of the identified deficiencies; (iv) the CMO's process for filling the vials was so flawed that the related deficiencies could not be resolved through the production of additional data alone, including the manual extraction study; (v) because the CMO's process for filling the vials was so flawed, it could only remedy deficiencies by changing its fill process to meet specifications; (vi) as a result, the CMO would need to conduct additional process qualification with subsequent validation data to support; and (vii) as a result of insufficient documentation and inadequate processes relating to filling

the vial, the CMO's ability to obtain the necessary data to assure the FDA that the identified deficiencies had been resolved would be delayed.

2. Partial Disclosure on April 14, 2021

315. On April 14, 2021, pre-market, CorMedix issued its 4/14/21 Press Release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, announcing "that it has met with the [FDA] to discuss proposed resolutions for the deficiencies identified in the [First CRL] to CorMedix and the Post-Application Action Letter received by the third-party manufacturer (CMO) from FDA for the [NDA] for DefenCath." Specifically, that press release disclosed, in relevant part, that "**[a]ddressing FDA's concerns regarding the qualification of the filing operation may necessitate adjustments in the process and generation of additional data on operating parameters for manufacture of DefenCath.**"

316. On this news, CorMedix's stock price fell $1.72 per share, or 18.36%, to close at $7.65 per share on April 15, 2021.

317. Despite this decline in the Company's stock price, CorMedix securities continued to trade at artificially inflated prices throughout the remainder of the Class Period as a result of the CorMedix Defendants' continued misrepresentations and omissions regarding the true scope of the existing deficiencies at the facility manufacturing DefenCath and with the manufacturing process itself. Moreover, the CorMedix Defendants made materially false and

misleading statements and/or failed to disclose material facts relating to the amount of time it would take the CMO to ectify these deficiencies.

318. First, after assuring investors that "[r]epresentatives from both CorMedix and the CMO participated in the meeting with FDA to ensure that there is alignment on addressing the [FDA]'s concerns[,]" the 4/14/21 Press Release stated, in relevant part, that:

> ***CorMedix and the CMO are currently evaluating available data to determine if additional process qualification will be needed with subsequent validation to address these issues.***
>
> The FDA stated that the review timeline would be determined when the NDA resubmission is received and that it expected all corrections to facility deficiencies to be complete at the time of resubmission so that all corrective actions may be verified during an on-site evaluation in the next review cycle, if the FDA determines it will do an onsite evaluation***. CorMedix and the CMO continue to work closely to ensure that the identified deficiencies are resolved*** prior to resubmission of the DefenCath NDA.
>
> ***CorMedix will provide updates on the timeline as resolution of the deficiencies proceeds.***

319. Next, CorMedix's Corporate Presentation, issued on April 14, 2021, provided a "Manufacturing Overview: Supply Chain Substantially Completed; Launch Quantities in Production", stating, in relevant part, that CorMedix had "***[s]uccessfully concluded technical transfer and validation of the drug product manufacturing process***, which has enabled production at 2 different manufacturing

locations[,]" and that "***[l]aunch quantities are already in production***[.]"[141]

320. The statements referenced in ¶¶318-19 were materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) despite claims of "work[ing] closely" with the CMO, the CorMedix Defendants had failed to ensure processes were in place to assure the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (ii) the CMO's existing documentation was insufficient to show its methods of manufacturing and quality controls met cGMP standards; (iii) as a result, it would be necessary for the CMO to collect additional data, including but not limited to, an airflow visualization study, in order to achieve resolution of the identified deficiencies; (iv) the CMO's process for filling the vials was so flawed that the related deficiencies could not be resolved through the production of additional data alone, including the manual extraction study; (v) because the CMO's process for filling the vials was so flawed, it could only remedy deficiencies by changing its fill process to meet specifications; (vi) as a result, the CMO would need to conduct additional process qualification with subsequent validation data to support; and (vii) as a result of insufficient documentation and

[141] *Corporate Presentation*, CORMEDIX, INC. (Apr. 14, 2021) ("April 2021 Presentation") https://www.cormedix.com/wp-content/uploads/2021/04/CorMedix_Corporate-Presentation_4-14-21-v3.pdf.

inadequate processes relating to filling the vial, the CMO's ability to obtain the necessary data to assure the FDA that the identified deficiencies had been resolved would be delayed.

3. Partial Disclosure on May 13, 2021

321. On May 13, 2021, during post-market hours, CorMedix issued its 5/13/21 Press Release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, reporting its results for the first quarter of 2021 ("1Q21") and providing a business update. That press release revealed, in relevant part, that "**[b]ased on [CorMedix's] analyses, we have concluded that additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA**."

322. Later that same day, also during post-market hours, the CorMedix Defendants hosted a conference call with investors and analysts to discuss, among other things, CorMedix's progress with the DefenCath NDA.[142] During the 1Q21 Call, Defendant Mounts reiterated this disclosure, providing, in relevant part, that:

> As we have explained previously, the major focus of FDA's concerns was on the qualification of the filling operation and CorMedix and the CMO have been evaluating available data to assess the need for adjustments in the manufacturing process and generation of additional

[142] *CorMedix, Inc. (CRMD) CEO Khoso Baluch on Q1 2021 Results - Earnings Call Transcript*, SEEKING ALPHA (May 13, 2021, 04:30 PM ET) ("1Q21 Call"), https://seekingalpha.com/article/4428474-cormedix-inc-crmd-ceo-khoso-baluch-on-q1-2021-results-earnings-call-transcript.

data on operating parameters for manufacture of DEFENCATH.

> Based on our analysis, we have concluded that additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA. As a result, ***our current plan is to be able to resubmit the [DEFENCATH] NDA in [4Q21]***.

323. Then, during the Q&A Session of the 1Q21 Call, *JMP* analyst Jason Butler asked "in terms of the additional in process qualification work, have you already agreed with your CMO what the plan is there? And what needs to be done? And is there any granularity you can give us in terms of timeline[] to complete that work?" To which, Defendant Mounts responded:

> Yes, we have agreed with the CMO on the plan to go forward to resolve the deficiencies and generate the additional data required by FDA. As we have said, the **FDA has focused on the in-process controls and has requested some additional data on the process qualification**. And as a result of that, we will be **required to manufacture the validation batches** to fulfill the request from the agency.

324. Dissatisfied with the CorMedix Defendants' continued ambiguous and general descriptions of the deficiencies identified with regards to the CMO's filling operations and the need for additional qualification processes and validation data, Needham analyst Chad Messer, pressed for clearer details on these deficiencies and the Company's anticipated timeline for achieving the resolution of them prior to the 4Q21 NDA submission.

325. When specifically pressed for these additional details, Defendant Mounts disclosed, in relevant part:

> [I]t is a complicated process and that it is not simple, and **like all**

technical work, needs to be conducted with precision and is subject to issues when something can go wrong. It is highly sophisticated equipment. **And so there are times when there may be unexpected results obtained.**

FDA's concern as they express[ed] to us during our meetings with them focused on the filling operation, which is the process by which DEFENCATH is during a sterile procedure loaded into the vials and then the vials are kept.

They expect us to generate sufficient data to demonstrate that, that process is a controlled process and is consistent with the agency's requirements for good manufacturing practice. So clearly, sterility is a very important part of that process, but also **the accuracy in making sure the right volume of DEFENCATH is loaded into the vials.** And we are talking about thousands of vials during the manufacturing run.

So as I said, it is a complicated process and technically very involved and involves a generation of a lot of data to make sure that the process itself is using the jargon qualified, which means all the equipment has been qualified for the intended use and every step in the manufacturing process has been qualified.

And that everything works as it is intended to produce the product that has to meet its specifications**.** So they are very detailed requirements on a chemical basis as well on a performance basis that is required for the product.

And so that **process needs to be very robust, needs to be reproducible.** And the burden is on the manufacturer to demonstrate that the facility can do that process reducibly and generate the required product for commercial distribution.

326. On this news, CorMedix's stock price fell $1.51 per share, or 19.97%, to close at $6.05 per share on May 14, 2021.

327. Despite this decline in the Company's stock price, CorMedix securities continued to trade at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misrepresentations and

omissions regarding the true scope of the deficiencies at the facility manufacturing DefenCath and with the manufacturing process itself. Moreover, the CorMedix Defendants made materially false and misleading statements and/or failed to disclose material facts relating to the amount of time it would take the CMO to try and rectify these deficiencies.

328. For example, the 5/13/21 Press Release stated, in relevant part, that "***CorMedix successfully completed the agreed upon protocol for the manual extraction study identified in the Complete Response Letter*** that FDA is requiring ***as confirmation of in-process controls to demonstrate that the labeled volume can be consistently withdrawn from the vials***."

329. In addition, Defendant Baluch is quoted in the 5/13/21 Press Release as stating, in relevant part, "As we continue to work through the items required by FDA for resubmission of the NDA, we remain confident in our efforts[,]" and "[w]e believe ***we have the right team and resources to accomplish this as we advance DefenCath through the regulatory approval process***."

330. Similarly, during the 1Q21 Call, Defendant Baluch stated, in relevant part, that "[w]e remain confident that ***we have the right team and appropriate resources in place to resolve the third-party manufacturing deficiency***."

331. Also, during the 1Q21 Call, Defendant Mounts went on to add, in relevant part, that:

> As we previously discussed, the [] CRL, sent to CorMedix by the FDA required ***a manual extraction study to demonstrate that the labeled volume of DEFENCATH can be consistently withdrawn from the vials to confirm the manufacturing in process controls.***
>
> I am pleased to report that the study has been completed successfully. As noted by [Defendant Baluch], we announced after the meeting with FDA that we had an agreed-upon protocol that has now been executed.
>
> The data clearly demonstrate consistent withdrawal of the labeled volume from the vials. ***The CorMedix CMC and regulatory teams continue to focus our efforts on resolving the deficiencies [sent] to the [] CMO***, in the post application action letter.

332. That same day, CorMedix filed a quarterly report on Form 10-Q with the SEC, reporting its financial and operating results for the quarter ended March 31, 2021.[143] The 1Q21 10-Q further assured investors that "***[t]he Company and the CMO continue to work closely to ensure that the identified deficiencies are resolved*** prior to resubmission of the DefenCath NDA."

333. Appended as exhibits to the 1Q21 10-Q were substantively the same SOX certifications referenced in ¶263, *supra*, signed by Defendants Baluch and David.

334. The statements referenced in ¶¶328-33 were materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) despite claims of "work[ing] closely" with the CMO, the CorMedix Defendants had failed to ensure the methods used in

[143] CorMedix, Inc., Quarterly Report (Form 10-Q) (May 13, 2021) ("1Q21 10-Q").

manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (ii) the CMO's existing documentation was insufficient to show its methods of manufacturing and quality controls met cGMP standards; (iii) as a result, it would be necessary for the CMO to collect additional data, including but not limited to, an airflow visualization study, in order to achieve resolution of the identified deficiencies; (iv) the CMO's process for filling the vials was so flawed that the related deficiencies could not be resolved through the production of additional data alone, including the manual extraction study; and (v) as a result of insufficient documentation and inadequate processes relating to filling the vial, the CMO's ability to obtain the necessary data to assure the FDA that the identified deficiencies had been resolved would be delayed and the Company would not resubmit its NDA in 4Q21.

335. Then, on August 12, 2021, CorMedix issued its 8/12/21 Press Release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, reporting its 2Q21 results and providing a business update. That press release stated, in relevant part, that "CorMedix remains focused in its efforts to resolve the deficiencies sent to the third-party manufacturer in the Post-Application Action Letter and ***remains on schedule to re-submit the DefenCath™ New Drug Application in [4Q21]***."

336. Later that day, Defendants hosted the Company's 2Q21 Call with investors and analysts at 4:30 ET to discuss, among other things, its progress with the addressing the deficiencies identified by the FDA and its work to resubmit the DefenCath NDA in 4Q21. On that call, Defendant Baluch stated, in relevant part, during his opening remarks:

> During the last earnings call on May 13, we provided an update on the progress that CorMedix has made to date on addressing the deficiencies identified by the FDA as the third-party manufacturing facility. The work has continued and we are reiterating that ***at present, we are on schedule to be able to resubmit the CorMedix NDA in quarter 4, 2021.***
>
> * * *
>
> We are also balancing our preparation for launching DEFENCATH while limiting our cash burn so that ***financially we have the resources required to efficiently bring DEFENCATH to patients in the U.S. market when FDA approval is received.***
>
> * * *
>
> To summarize, ***we continue to focus our effort expeditiously resolving the third-party manufacturing deficiencies with a plan to resubmit in quarter 4, 2021.*** We are carefully balancing our cash burn, while preparing for the launch of DEFENCATH ***once we have approval of the NDA by the FDA***.
>
> * * *
>
> We remain confident that ***we have the right team and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified*** and bring DEFENCATH to hemodialysis patients in the U.S.

337. In addition, Defendant Mounts stated, in relevant part, that:

> I will start by assuring you that ***we remain on schedule to resubmit the new drug application or NDA in [4Q21]***. We have continued to work diligently to resolve deficiencies identified by FDA as a third-party manufacturing facility or CMO.

> As I have explained previously, we have ***successfully completed the manual extraction study required by FDA*** and the Complete Response Letter or CRL sent by the FDA to CorMedix. ***We have demonstrated that the labeled volume of DEFENCATH can be consistently withdrawn from the v[ials].***
>
> Also, as we have explained previously, resolution of the deficiencies at the manufacturing facility identified in the post-application action letter sent to the CMO has required additional process qualification with subsequent validations for the vial filling process. The process qualification and validation are done by the manufacturing facility and ***we are working closely with them and CMC consultants engaged by CorMedix to ensure that we are addressing FDA concerns appropriately***.
>
> The deficiencies communicated to the CMO by FDA need to be satisfactorily addressed for approval of the DEFENCATH NDA. ***The CMC and regulatory teams of CorMedix are working collaboratively with the CMO to ensure the generation of the required data and documentation to resubmit the NDA in [4Q21]***.

338. During the Q&A Session of the 2Q21 Call, *Truist* analyst Joon Lee asked, "[r]egarding the process qualification of vials and the vial filling process, and the manual extraction studies. Did those require production of new batches of DEFENCATH? And if so, will you need stability data from those new batches before you can submit the NDA or during the process of NDA [Indiscernible]?" In response, Defendant Mounts stated:

> [A]s I've explained, we need to do some, as you said, process qualification. And then you need to validate that by generating additional batches and part of the program for any manufactured batches that are intended for commercial use, or to put those batches into a stability program, and to generate stability data to demonstrate in fact that the product is stable and continues to meet specifications.
>
> ***We have an abundance of data on stability of other batches that have been produced. And so we expect to be able to show consistency.***

339. The statements referenced in ¶¶335-38 were materially false and misleading because the Company had neither "successfully" demonstrated fill consistency nor had "an abundance of data on stability of other batches" that met FDA standards. In addition, they failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the CMO's existing documentation was insufficient to show its methods of manufacturing and quality controls met cGMP standards; (ii) as a result, it would be necessary for the CMO to collect additional data, including but not limited to, an airflow visualization study, in order to achieve resolution of the identified deficiencies; (iii) the CMO's process for filling the vials was so flawed that the related deficiencies could not be resolved through CorMedix's production of additional data alone, *i.e.*, the manual extraction study; (iv) at all relevant times, the CMO manufactured multiple different drug products using the same manufacturing lines, yet, despite claims of "work[ing] closely" with the CMO, the CorMedix Defendants failed to ensure that the CMO's protocols relating to changeover of manufacturing lines and its processes for visual inspection of the drug product met cGMP standards; (v) as a result of deficient changeover protocols and visual inspections processes, the CMO manufactured contaminated vials; and (vi) as a result of insufficient documentation and the foregoing deficiencies at the CMO's manufacturing facilities, its ability to obtain the necessary data to assure the FDA that the identified deficiencies had been resolved

would be delayed and CorMedix could not resubmit its NDA in 4Q21.

4. Partial Disclosure on September 7, 2021

340. Then, on September 7, 2021 at 8:30 AM ET, the Company issued its 9/7/21 Press Release, disclosing that "**CorMedix has encountered delays at its third-party [CMO]**" relating to "issues that are unrelated to DefenCath manufacturing activities" and that "**the timeline for CorMedix and the CMO to address deficiencies** at the facility that are required for resubmission of the DefenCath NDA **is uncertain at this time**."

341. On this news, CorMedix's stock price fell $1.77 per share, or 27.40%, to close at $4.69 per share on September 9, 2021.

342. Analysts attributed the Company's stock price decline to the now uncertain resubmission deadline. As a September 7, 2021 article by the Motley Fool titled "Why CorMedix Stock Is Getting Crushed Today" noted, the Company's "stock was getting crushed on Tuesday, with shares down 23.7% as of 11 a.m. EDT … after the company announced that it 'has encountered delays at its third-party contract manufacturer.' These delays will push back CorMedix's refiling for [FDA] approval of its DefenCath antibacterial and antifungal catheter lock solution by an undetermined amount of time."[144]

[144] 9/7/21 Motley Fool; *see also* 9/7/21 SEEKING ALPHA ("CorMedix's stock price "slump[ed] 20.6% premarket after the company provided an update with respect to its resubmission timeline for the DefenCath [NDA]")

343. While industry analysts following CorMedix also understood its disclosure to mean that the "**CMO delay brings uncertainty to Defencath NDA resubmission timelines**," they were still bullish on the Company because they were able to "**confirm[] with management** that CorMedix continues to maintain a very good working relationship with its CMO and there is still full agreement on the work needed to complete the NDA resubmission."[145]

344. Thus, despite the decline in the Company's stock price, CorMedix securities continued to trade at artificially inflated prices throughout the rest of the Class Period as a result of the CorMedix Defendants' statements. Specifically, they misrepresented their CMO's ability to pass an FDA on-site inspection while concealing ongoing manufacturing issues at the facility that was manufacturing DefenCath, and misrepresented potential supply chain risks while concealing that risks had materialized due to the FDA's concerns about manufacturing deficiencies observed during an on-site inspection of their heparin supplier's facility.

345. On February 28, 2022, CorMedix issued a press release announcing its resubmission of the DefenCath NDA addressing the manufacturing deficiencies identified by the FDA a year prior.[146] That press release quoted Defendant Mounts

[145] Jason N. Butler, PhD, Roy Buchanan, PhD, *Defencath Announcement Increases Timing Uncertainty, but Fundamental Impact Unlikely*, JMP SECURITIES LLC (Sep. 7, 2021).

[146] 2/28/22 Press Release.

as stating, in relevant part, that "***we and the manufacturer have adequately addressed the concerns the [FDA] identified in the CRL and PAAL***."

346. On March 28, 2022, CorMedix issued a press release announcing FDA acceptance of the DefenCath NDA resubmission, explaining that it was considered a Class 2 response warranting a re-inspection of the Company's CMO's facilities.[147] That press release quoted Defendant Mounts as stating, in relevant part, that "***both CorMedix and our contract manufacturer have adequately addressed the concerns the Agency identified during the review of the original NDA***..."

347. The next day, on March 29, 2022, CorMedix hosted a conference call with investors and analysts at 4:30 ET to discuss, among other things, the financial results for the fourth quarter 2021.[148] During her opening remarks, Defendant Mounts stated that "***CorMedix and the [CMO] have adequately addressed the concerns identified by FDA***...."

348. The statements referenced in ¶¶345-47 were materially false and misleading because (i) the CorMedix and its CMO **had not** "adequately addressed the concerns identified by the FDA" and (ii) failed to disclose material adverse facts about CorMedix's business and operations, including that it had not ensured its

[147] 3/28/22 Press Release.

[148] 4Q21 Call.

CMO complied, or even had sufficient knowledge and/or understanding to comply, with cGMP standards.

349. Defendant Mounts further confirmed that "***[w]e are committed to providing updates to investors as appropriate*** over the coming months during the review process."

350. The statement referenced in ¶349 was materially false and misleading because Defendants made material misstatements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that (i) CorMedix had not ensured its CMO complied, or even had sufficient knowledge and/or understanding to comply, with cGMP standards; (ii) the Company was not "committed to providing updates to investors" and in fact, had hid the most damaging and important information from investors; and (iii) that the FDA had already observed manufacturing deficiencies at the third-party facility supplying the key active ingredient heparin for CorMedix which warranted the issuance of a Form 483 on February 4, 2022 and requests for corrective actions – adding high risk to the FDA approving the second DefenCath NDA.

351. In addition, Defendant Mounts stated that "it is important to anticipate ***potential supply chain challenges*** and ensure multiple sources are in place to provide adequate inventory."

352. The statement referenced in ¶351 was materially false and misleading

because it (i) omitted that the CorMedix Defendants had never "ensure[d] multiple sources [were] in place to provide adequate inventory" and (ii) failed to disclose material adverse facts about CorMedix's business and operations, including that the FDA had already observed manufacturing deficiencies at the third-party facility supplying the key active ingredient heparin for CorMedix which warranted the issuance of a Form 483 on February 4, 2022 and requests for corrective actions – adding high risk to the FDA approving the second DefenCath NDA. Thus, the risk of "potential supply chain challenges" had already materialized, unbeknownst to investors. And yet Defendant Mounts said nothing about the manufacturing issues at the Company's heparin supplier's facility.

353. On May 12, 2022, CorMedix hosted a conference call with investors and analysts at 4:30 ET to discuss, among other things, the financial results for the first quarter 2022.[149] During his opening remarks on that call, Defendant Todisco stated, in relevant part "***any FDA inspection of our CMO will assess the commercial readiness of the facility and manufacturing operations beyond those specific to DefenCath***."

354. The statement referenced in ¶353 was materially false and misleading because the FDA had expressly told CorMedix that it had concerns about its CMO and fill process that were "specific to DefenCath."

[149] 1Q22 Call.

355. In addition, Defendant Todisco noted that "from a supply chain standpoint, ***we're also continuing initiatives to dual source key components and active ingredients in order to de-risk … potential governmental regulatory actions at any key supplier***."

356. Later during the 1Q22 Call, Needham analyst Rohit Bhasin followed up asking about "what kind of preparations are you guys making in terms of launch in terms of … manufacturing supply ahead of time?" Defendant Todisco responded:

> On the launch prep side, when – ***in terms of activities that we are currently undertaking, we are doing right now all the typical prelaunch planning***. We are building out our commercial plan, building out our core messaging, doing our pricing studies, building our staffing plans. But most importantly, we are engaging those reimbursement activities and engaging key stakeholders to work with CMS, and we see that as one of the most critical components of our launch strategy.

357. The statements referenced in ¶¶355-56 were materially false and misleading because the CorMedix Defendants had not "de-risk[ed]" "governmental regulatory actions at any key supplier," and the statements failed to disclose material adverse facts about CorMedix's business and operations, including that the FDA had already observed manufacturing deficiencies at the third-party facility supplying the key active ingredient heparin for CorMedix which warranted the issuance of a Form 483 on February 4, 2022 and requests for corrective actions – adding high risk to the FDA approving the second DefenCath NDA. Thus, the risk of "potential governmental regulatory actions at any key supplier" had already materialized,

unbeknownst to investors. And yet Defendant Todisco said nothing about the manufacturing issues at the Company's heparin supplier's facility – even when specifically asked about "manufacturing supply."

358. On June 15, 2022, Defendant Todisco presented at the JMP Securities Life Sciences Conference to discuss, among other things, the "attractive investment opportunity" in CorMedix and DefenCath.[150] During the presentation, Todisco was told that investors "are focused on the manufacturing inspection process" and was asked "[i]s everything there moving forward and still gives you confidence that that can be completed in time to enable an approval later this quarter?" In response, Todisco stated in relevant part:

> ***So from everything that we can see***, I'm optimistic that everything is moving in the right direction.
>
> * * *
>
> ***[T]he big obstacle does appear to be the FDA's inspection at the site.*** … As any FDA inspection does, I expect there will be observations that have to be responded to. And we are going to work closely with our CMO for any observations that are related to DefenCath.
>
> I think that one of the key variables, though, is that ***this is an inspection of facility that is larger than just the manufacturing operations related to DefenCath.*** So to the extent that there are any observations that don't involve our product, we may not have the ability to work with our CMO in those responses or have full visibility.
>
> But I believe that our contract manufacturer is a reputable -- highly reputable European manufacturer. I think ***they're going to take all care to work diligently through any observations and work with the FDA on, if necessary, improving any compliance concerns FDA could***

[150] *JMP* Transcript.

raise.

359. The statements referenced in ¶358 were materially false and misleading because (i) "everything [the CorMedix Defendants] could see" did not actually indicate that things were "moving in the right direction," including the fact that the FDA was still criticizing CorMedix's manufacturing process, and (ii) the statements failed to disclose material adverse facts about CorMedix's business and operations, including that CorMedix had not ensured that its CMO complied, or even had sufficient knowledge and/or understanding to comply, with cGMP standards. Further, "everything that we can see" included that the FDA had observed manufacturing deficiencies at the third-party facility supplying heparin for CorMedix which warranted the issuance of a Form 483 on February 4, 2022 and requests for corrective actions – adding high risk to the FDA approving the second DefenCath NDA.

D. The Truth Fully Emerges

360. After markets closed on August 8, 2022, CorMedix admitted that manufacturing issues at its CMO still existed through its announcement of yet another CRL "from the FDA stating that the DefenCath NDA cannot be approved until deficiencies recently conveyed to the [CMO] and the supplier of the [API] heparin during inspections are resolved to the satisfaction of FDA."[151] Despite

[151] 8/8/22 Press Release.

deficiencies in the manufacturing of another drug at the CMO's facility impacting FDA approval of DefenCath, CorMedix again apparently did not sufficiently prepare for "the FDA conduct[ing] a recent inspection unrelated to DefenCath at the facility of the company's heparin supplier, which culminated in the API supplier receiving a warning letter as a result of manufacturing deficiencies for a non-heparin API." As a result, "by way of the CRL, the FDA has now informed the company that satisfactory resolution of these deficiencies will be required before the DefenCath NDA may be approved."

361. On this news, CorMedix's stock price fell $4.32 per share, or 57.45%, to close at $3.20 per share on August 9, 2022.

362. As SA News Editor Anuron Mitra noted on August 8, 2022, CorMedix's "new drug application for its antibacterial and antifungal solution DefenCath had been rejected by the U.S. FDA for a second time, sending its shares plunging 60.1% to $3 after hours."[152]

363. Analysts following the Company understood from its August 8, 2022 disclosure that manufacturing deficiencies continued to be the issue:

- "CorMedix disclosed receipt of a Complete Response Letter for DefenCath, solely noting ***outstanding*** manufacturing-related

[152] *FDA again rejects CorMedix's application for lead candidate DefenCath, shares sink ~60*, SEEKINGALPHA, (Aug. 8, 2022), https://seekingalpha.com/news/3869456-fda-again-rejects-cormedixs-application-for-lead-candidate-defencath-shares-sink-60.

deficiencies."[153]

- "**CorMedix Inc. (CRMD)** CMC Issues Strike Again…"[154]

364. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

E. Loss Causation

365. The false and misleading misrepresentations and material omissions, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class members he represents.

366. During the Class Period, as detailed herein, Plaintiff and the 1934 Act Class members purchased CorMedix securities at artificially inflated prices and were damaged thereby. The price of the Company's securities declined significantly when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were disseminated and publicly revealed.

367. During the Class Period, the CorMedix Defendants materially misled the investing public, thereby inflating the price of CorMedix securities, by publicly

[153] Jason N. Butler, PhD, Roy Buchanan, PhD, *More Manufacturing Speedbumps but Readily Addressable, In Our View*, JMP SECURITIES LLC (Aug. 9, 2022).

[154] Joon Lee, M.D., Ph.D., Les Sulewski, *CMC Issues Strike Again. But We Think They're Remediable In Short Period.* TRUIST SECURITIES, INC (Aug. 8, 2022).

issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make the statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about CorMedix's business, operations, and prospects, as alleged herein.

368. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the 1934 Act Class. The CorMedix Defendants made or caused to be made materially false and/or misleading statements about CorMedix's business, operations and future prospects. These material misstatements and/or omissions had the cause and effect of creating in the market a false positive assessment of the Company and its business and operational performance and related well-being, thus causing its securities to be overvalued and the price of its securities to be artificially inflated at all relevant times. Defendants' materially false and/or misleading statements, as alleged herein, resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was partially revealed March 1, 2021, April 14, 2021, May 13, 2021, September 7, 2021, and then fully on August 8, 2022, causing the trading price of CorMedix securities to materially decline and removing the

previously embedded artificial inflation.

F. No Safe Harbor

369. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false statements alleged in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

370. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of CorMedix who knew that the statement was false and/or misleading when made.

G. Class Action Allegations by the 1934 Act Class

371. Plaintiff brings this action as a class action pursuant to Rules 23(a) and (b)(3) on behalf of all persons and entities who purchased or otherwise acquired

CorMedix securities between October 16, 2019 and August 8, 2022, inclusive (the "Class Period"). This class of investors asserts claims only for violations of Sections 10(b) and 20(a) of the 1934 Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.1 b-5 (the "1934 Act Class"). Excluded from the 1934 Act Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

372. The members of the 1934 Act Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, CorMedix securities were actively traded on the NASDAQ and NYSE. While the exact number of 1934 Act Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed 1934 Act Class. Record owners and other members of the Class may be identified from records maintained by CorMedix or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

373. Plaintiff's claims are typical of the claims of the 1934 Act Class members as all members of the 1934 Act Class are similarly affected by Defendants' wrongful conduct, in violation of federal securities law, complained of herein.

374. Plaintiff will fairly and adequately protect the interests of the members of the 1934 Act Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the 1934 Act Class.

375. Common questions of law and fact exist as to all members of the 1934 Act Class and predominate over any questions solely affecting individual members. Among the questions of law and fact common to the 1934 Act Class are:

- whether federal securities laws were violated by the CorMedix Defendants' acts as alleged herein;
- whether statements made by the CorMedix Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of the Company;
- whether the Officer Defendants caused CorMedix to issue false and misleading financial statements during the Class Period;
- whether the CorMedix Defendants acted knowingly or recklessly in issuing false and misleading statements;
- whether the prices of the Company's securities during the Class Period were artificially inflated because of the CorMedix Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

376. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual members of the 1934 Act Class may be relatively small, the expense and burden of individual litigation makes it impossible for them to individually redress the wrongs done to

them. There will be no difficulty in the management of this action as a class action.

377. Plaintiff and the other members of the 1934 Act Class will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that, *inter alia*: (a) the CorMedix Defendants made public misrepresentations or failed to disclose material facts; (b) the omissions and misrepresentations were material; (c) the Company's securities traded in an efficient market; (d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and (e) Plaintiff and the other members of the 1934 Act Class purchased CorMedix securities between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

378. At all relevant times, the market for CorMedix securities was efficient for the following reasons, among others: (a) CorMedix securities met the listing requirements for, and were listed and actively traded on the NASDAQ and the NYSE, highly efficient markets; (b) during the Class Period, CorMedix shares were actively traded, supporting a strong presumption of efficiency; (c) CorMedix issued public reports with the SEC; (d) CorMedix regularly communicated with public investors, including via regular disseminations of press releases on major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; (e) CorMedix was followed

by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force, certain customers of their respective brokerage firms, and were publicly available; and (f) unexpected material news about CorMedix was rapidly reflected in and incorporated into the price of its securities during the Class Period.

379. Because CorMedix is a publicly traded company, the CorMedix Defendants knew, understood and had reason to expect that: (1) their misstatements would artificially inflate the price of CorMedix securities; (2) investors would rely on the price of CorMedix common stock as reflecting accurate information known to CorMedix and its executives; and (3) their misstatements and omissions would induce Plaintiff and the other members of the 1934 Act Class to purchase CorMedix securities during the Class Period.

380. As a result of the foregoing, the market for CorMedix's securities promptly digested current information regarding the Company from all publicly available sources and reflected such information in CorMedix's share price. Under these circumstances, all purchasers of CorMedix's securities during the Class Period suffered similar injury through their purchase of CorMedix's securities at artificially inflated prices and a presumption of reliance applies.

381. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United*

States, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on the CorMedix Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding CorMedix's business, operations, and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

COUNT I
Violations of § 10(b) of the 1934 Act and Rule 10b-5
(Against the CorMedix Defendants)

382. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

383. This Count is asserted against the CorMedix Defendants and is based upon § 10(b) of the 1934 Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder.

384. During the Class Period, the CorMedix Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the 1934 Act

Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other 1934 Act Class members, as alleged herein; (ii) artificially inflate and maintain the market price of CorMedix securities; and (iii) cause Plaintiff and other members of the 1934 Act Class to purchase or otherwise acquire CorMedix securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, the CorMedix Defendants took the actions set forth herein.

385. Pursuant to the above plan, scheme, conspiracy and course of conduct, each Officer Defendant named herein participated directly or indirectly in preparing and/or issuing quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for CorMedix securities. Such reports, filings, press releases and other statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about CorMedix's finances and business prospects.

386. By virtue of their positions at CorMedix, the Officer Defendants had

actual knowledge of the material misstatements and omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the 1934 Act Class, or, in the alternative, the Officer Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to the Officer Defendants.

387. Said acts and omissions of the CorMedix Defendants were committed willfully or with reckless disregard for the truth. In addition, each of the Defendants named herein knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

388. Information showing that the CorMedix Defendants acted knowingly or with reckless disregard for the truth is peculiarly within their knowledge and control. As the senior managers and/or directors of CorMedix, the Officer Defendants had knowledge of the details of the Company's internal affairs.

389. The Officer Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Officer Defendants were able to and did, directly or indirectly, control the content of the statements of CorMedix. As officers and/or directors of a publicly held company, the Officer Defendants had a duty to disseminate timely, accurate, and

truthful information with respect to CorMedix's business, operations, prospects, and future financial condition.

390. As a result of the dissemination of false and misleading public reports, releases and statements described herein, the market price of CorMedix securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning CorMedix's business and financial condition which were concealed by the CorMedix Defendants, Plaintiff and the other members of the 1934 Act Class purchased or otherwise acquired CorMedix securities at artificially inflated prices, relying upon the price of the securities, the integrity of the market for the securities, and/or upon statements disseminated by Defendants, and were damaged thereby.

391. Had Plaintiff and the other members of the 1934 Act Class known the truth, they would not have purchased or otherwise acquired them at the inflated prices that were paid, or at all. At the time of the purchases and/or acquisitions by Plaintiff and the 1934 Act Class, the true value of CorMedix securities was substantially lower than the prices paid. The market price of CorMedix securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and the 1934 Act Class members.

392. By reason of the conduct alleged herein, the CorMedix Defendants, knowingly or recklessly, directly, or indirectly, violated § 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder.

393. As a direct and proximate result of the CorMedix Defendants' wrongful conduct, Plaintiff and the other members of the 1934 Act Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II
Violations of § 20(a) of the 1934 Act
(Against the Officer Defendants)

394. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

395. During the Class Period, the Officer Defendants participated in the operation and management of CorMedix, and conducted and participated, directly and indirectly, in the conduct of CorMedix's business affairs. Because of their senior positions, they knew the adverse non-public information about CorMedix's misstatement of income and expenses and false financial statements. As officers and/or directors of a publicly owned company, the Officer Defendants had a duty to disseminate accurate and truthful information with respect to CorMedix's financial condition and results of operations, and to correct promptly any public statements issued by CorMedix which had become materially false or misleading.

396. Because of their positions of control and authority as senior officers, the Officer Defendants were able to, and did, control the contents of the various

reports, press releases and public filings which CorMedix disseminated in the marketplace during the Class Period concerning its results of operations. Throughout the Class Period, the Officer Defendants exercised their power and authority to cause CorMedix to engage in the wrongful acts complained of herein. The Officer Defendants, therefore, were "controlling persons" of CorMedix within the meaning of § 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of CorMedix securities.

397. Each of the Officer Defendants, therefore, acted as a controlling person of CorMedix. By reason of their senior management positions and/or being directors of CorMedix, each of the Officer Defendants had the power to direct the actions of, and exercised the same to cause, CorMedix to engage in the unlawful acts and conduct complained of herein. Each of the Officer Defendants exercised control over the general operations of CorMedix and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

398. By reason of the above conduct, the Officer Defendants are liable pursuant to § 20(a) of the Exchange Act for the violations committed by CorMedix.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and the other member of the Classes, prays for relief and judgment against as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23, and certifying Plaintiff as the Class representative;

B. Awarding compensatory damages in favor of Plaintiff and the other members of the Classes against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Classes their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding Plaintiff and other members of the Classes such other and further relief as this Court may deem just and proper.

VII. DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: October 10, 2022

Respectfully Submitted,

ROCHE FREEDMAN LLP

/s/ Ivy T. Ngo
Ivy T. Ngo (*pro hac vice*)
Velvel (Devin) Freedman (*pro hac vice*)
Constantine P. Economides (*pro hac vice* forthcoming)
1 SE 3rd Ave., Suite 1250
Miami, Florida 33131
Telephone: (305) 971-5943
ingo@rochefreedman.com
vel@rochefreedman.com
ceconomides@rochefreedman.com

POMERANTZ LLP
Josh Silverman (*pro hac vice*)
Louis C. Ludwig
10 South LaSalle St., Ste. 3505
Chicago, IL 60603
Telephone: (312) 377-1181
jpsilverman@pomlaw.com
lcludwig@pomlaw.com

Thomas H. Przybylowski
600 Third Avenue
New York, New York 10016
Telephone: (212) 661-1100
Facsimile: (212) 661-8665
tprzybylowski@pomlaw.com

Counsel for Lead Plaintiff and the Class

THE SCHALL LAW FIRM
Brian Schall (*pro hac vice* forthcoming)
1880 Century Park East, Suite 404
Los Angeles, CA 90067
Telephone: (424) 303-1964
brian@schallfirm.com

BRONSTEIN, GEWIRTZ, & GROSSMAN, LLC
Peretz Bronstein
Eitan Kimelman
60 East 42nd Street, Suite 4600
Telephone: (212) 697-6484
peretz@bgandg.com
eitank@bgandg.com

Additional Counsel for Lead Plaintiff

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Plaintiff, by his attorneys, hereby certifies that to the best of his knowledge, the matter in controversy is not related to any other action. Plaintiff is not currently aware of any other party who should be joined in this action.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: October 10, 2022

Respectfully Submitted,

ROCHE FREEDMAN LLP
/s/ Ivy T. Ngo
Ivy T. Ngo (*pro hac vice*)
Velvel (Devin) Freedman (*pro hac vice*)
Constantine P. Economides (*pro hac vice* forthcoming)
1 SE 3rd Ave., Suite 1250
Miami, Florida 33131
Telephone: (305) 971-5943
ingo@rochefreedman.com
vel@rochefreedman.com
ceconomides@rochefreedman.com

POMERANTZ LLP
Josh Silverman
Louis C. Ludwig
10 South LaSalle St., Ste. 3505
Chicago, IL 60603
Telephone: (312) 377-1181
jpsilverman@pomlaw.com
lcludwig@pomlaw.com

Thomas H. Przybylowski
600 Third Avenue

New York, New York 10016
Telephone: (212) 661-1100
Facsimile: (212) 661-8665
tprzybylowski@pomlaw.com

Counsel for Lead Plaintiff and the Class

THE SCHALL LAW FIRM
Brian Schall (*pro hac vice* forthcoming)
1880 Century Park East, Suite 404
Los Angeles, CA 90067
Telephone: (424) 303-1964
brian@schallfirm.com

BRONSTEIN, GEWIRTZ, & GROSSMAN, LLC
Peretz Bronstein
Eitan Kimelman
60 East 42nd Street, Suite 4600
Telephone: (212) 697-6484
peretz@bgandg.com
eitank@bgandg.com

Additional Counsel for Lead Plaintiff